Прилог 1 на ПОГЛАВЈЕ IV

ТАБЕЛА IV.1.1 Детали за суровини, меѓупроизводи, производи, итн. поврзани со процесите, за кои се употребуваат или создадени на локацијата вцц

Реф. Бр или шифра	Материјал/ Супстанција[1]	CAS[2] Број	Категорија на опасност[3)]	Количина (тони)	Годишна употреба (тони)	Природа на употребата	R[4] - Фраза	S[12] - Фраза
2000045	AMMONIA COMPRESSED	7664-41-7	8	2 ,3	14,5	Екстракција (во Фармација 1)	10-23-24-34-50	9-16-26-33-36-37-39-45-61
2000915	SODIUM HYDROXIDE TECHN. НАТРИУМ ХИДРОКСИД ТЕХН	1310-73-2	8	2,2	6,8	Екстракција (во Фармација 1)	36/38-35-34	26-45-37/39-24/25-29-36/37/39
2000327	CHARCOAL ACTIVATED ЈАГЛЕН МЕДИЦИНСКИ	16291-96-6	4.1	0	0,005	Прекристализација (во Фармација 2)	36/37-18-11	26-36
3000540	ACETIC ACID TECHN.	64-19-7	8	0	0,360	Прекристализација (во Фармација 2)	10-35	23-26-45
2000465	TARTARIC ACID TECHN.	87-69-4		0	0,370	Прекристализација (во Фармација 2)	36/37/38	26-36-37/39
2000475	HYDROCHLORIC ACID TECHN.	7647-01-0	8	0	10,2	Екстракција (во Фармација 1)	23-24-25-34-36-37-38	26-36-37-39-45
2000572	SULFURIC ACID TECHN.	7664-93-9	8	0	13,5	Екстракција (во Фармација 1)	36/38-35-39/23/24/25-23/24/25-11	26-30-45-36/37-16
2000575	CALCIUM HYDROXIDE TECHN. ХИДРИРАНА ВАР	1305-62-0	8	0	3	Екстракција (во Фармација 1)	41-34	26-39-45-36/37/39-27
2000577	АФИОНОВИ ШИШАРКИ			37,234	200 000	Екстракција (во Фармација 1)		
3000250	MORPHINE BASE	57-27-2				Прекристализација (во Фармација 2) Екстракција (во Фармација 1)	11-39/23/24/25	7-16-22-24/25-36/37-45-51

[1] Во случај каде материјалот вклучува одреден број на посебни и достапни опасни супстанции, дадете детали за секоја супстанција
[2] Chemical Abstracts Service
[3] Закон за превоз на опасни материи (Сл. Лист на СФРЈ бр. 27/90, 45/90, Сл. Весник на РМ 12/93)
[4] Според Анекс 2 од Додатокот на Упатството

ТАБЕЛА IV.1.2 Детали за суровини, меѓупроизводи, производи, итн. поврзани со процесите, а кои се употребуваат или создадени на локацијата

Реф. Бр или шифра	Материјал/ Супстанција[(1)]	Мирис			Приоритетни супстанции[5]			
		Миризливост Да/Не	Опис	Праг на осетливост μг/м^3				
2000045	AMMONIA COMPRESSED	да						
2000915	SODIUM HYDROXIDE TECHN. НАТРИУМ ХИДРОКСИД ТЕХН	не						
2000327	CHARCOAL ACTIVATED ЈАГЛЕН МЕДИЦИНСКИ	не						
3000540	ACETIC ACID TECHN.	да						
2000465	TARTARIC ACID TECHN.	не						
2000475	HYDROCHLORIC ACID TECHN.	да						
2000572	SULFURIC ACID TECHN.	не						
2000575	CALCIUM HYDROXIDE TECHN. ХИДРИРАНА ВАР	не						
2000577	АФИОНОВИ ШИШАРКИ	не						
3000250	MORPHINE BASE	не						

[5] Листа на приоритетни супстанции согласно Табелите III до VIII од Уредбата за класифицкација водите (Сл. Весник 18-99).

ТАБЕЛА V.2.1: ОТПАД - Користење/одложување на опасен отпад

Отпаден материјал	Број од Европскиот каталог на отпад	Главен извор[6,7]	Количина		Преработка/одложување во рамките на самата локација (Начин и локација)	Преработка, реупотреба или рециклирање со превземач (Метод, локација и превземач)	Одложување надвор од локацијата (Метод, локација и превземач)
			Тони/месечно	$м^3$ / месечно			

[6] За секој отпад треба да се посочи основната активност/процес
[7] Треба да се вклучи и отпадот прифатен на местото на локацијата за наменето искористување и одлагање на отпад

ТАБЕЛА V.2.2 ОТПАД - Друг вид на користење/одложување на отпад

Отпаден материјал	Број од Европски каталог на отпад	Главен извор[8]	Количина		Преработка/одложување во рамките на самата локација[9][10] (Метод, локација и превземач)	Преработка, реупотреба или рециклирање со превземач (Метод, локација и превземач)	Одложување надвор од локацијата (Метод, локација и превземач)
			Тони/месечно	$м^3$ / месечно			
Цврст отпад од мелени шишарки	02 03 99	мелење и екстракција	50		депонирање во земја		

[8] За секој отпад треба да се посочи основната активност/процес
[9] Методот на искористување или одлагање на отпадот треба да биде јасно опишан и посочен во Прилогот Е1.
[10] Треба да се вклучи и отпадот прифатен на местото на локацијата за наменето искористување и одлагање на отпад

ТАБЕЛА IV.1.1.1 Детали за суровини, меѓупроизводи, производи, итн. поврзани со процесите, а кои се употребуваат или создадени на локацијата

шифра	**Материјал/ Супстанција[3]**	**CAS[1] Број**	**Категорија на опасност[4)]**	**Количина** (тони)	**Годишна употреба** (тони)	**Природа на употребата**	**R[2] - Фраза**	**S[12] - Фраза**
258466	ALCOHOL	64-17-5	3	1	7	Таблетно, течно,масно	11,20,21,22, 36,37,38,40	7,16,24,25, 36, 37,39,45
224014	ALCOHOL DEHYDRATED	64-17-5	3	0.5	4	Таблетно, течно,ампулно	11,20,21,22, 36,37,38,40	7,16,24,25, 36, 37,39,45
200204	ANALGIN (METAMIZOLE SODIUM) TBL.GRADE	5907-38-0	нема податоци		47	таблетно		
215465	ANALGIN /METAMIZOLE SODIUM/AMP.GRADE	5907-38-0	нема податоци	0.4	3.6	ампулно		
210161	AVICEL PH 101/MYCROCRISTALINE CELLULOSE/	9004-34-6	не е ризичен	1.2	2.4	таблетно		
200948	AVICEL PH 102/MYCROCRISTALINE CELLULOSE/	9004-34-6	не е ризичен		21	таблетно		
213993	BHT /BUTYLHYDROXYTOLUENE/	128-37-0	не е ризичен	0.5	0.8	таблетно	22,36,37, 38,47	24
203416	CAFFEINE ANHYDROUS	58-08-2	6.1		8.6	Таблетно	22	
203629	CALCIUM CARBONATE HEAVY	471-34-1	не е ризичен	2.2	5.8	Таблетно,	36,37,38	26,36

[1] Chemical Abstracts Service
[2] Според Анекс 2 од Додатокот на Упатството
[3] Во случај каде материјалот вклучува одреден број на посебни и достапни опасни супстанции, дадете детали за секоја супстанција
[4] Закон за превоз на опасни материи (Сл. Лист на СФРЈ бр. 27/90, 45/90, Сл. Весник на РМ 12/93)

207365	CHLORPROPAMIDE	94-20-2	нема податоци	0.4	0.6	таблетно		
210617	CIPROFLOXACINE HCL MONOHYDRATE	86393-32-0	нема податоци	1.0	2	Таблетно, ампулно		
217344	COMPRITOL 888 ATO/GLYCERYL BEHENATE/	91052-55-0	нема податоци	0.3	1.1	таблетно		
213721	CROSCARMELLOSE SODIUM /AC-DI-SOL/	74811-65-7	нема податоци	0.7	1.7	таблетно		
205117	CUTINA HR/CASTOR OIL HYDROGENATED/	8001-78-3	не е ризичен		1.5	таблетно		
202401	D(-)-FRUCTOSE CRYSTALLINE	57-48-7	не е ризичен	1	4.8	Течно		
208655	DICAFOS C92-04/CALCIUM PHOSPH.DIB.ANHYD/	7757-93-9	не е ризичен	6.6	8.5	Таблетно	36,37,38	26
201871	DICAFOS C92-14/CALCIUM PHOSPH.DIB.DIHYD/	7789-77-7	не е ризичен	3.8	11	таблетно	36,37,38	
210781	DILTIAZEM HYDROCHLORIDE	33286-22-5		0.7	1.6	таблетно		
211737	FERROUS FUMARATE	141-01-5		0.7	3.5	Таблетно		
202436	GLYCERIN (GLICEROL) MEDICINSKI	56-81-5		4.3	1	Течно, ампулно		26,36

[1] Chemical Abstracts Service
[1] Според Анекс 2 од Додатокот на Упатството
[1] Во случај каде материјалот вклучува одреден број на посебни и достапни опасни супстанции, дадете детали за секоја супстанција
[1] Закон за превоз на опасни материи (Сл. Лист на СФРЈ бр. 27/90, 45/90, Сл. Весник на РМ 12/93)

213357	IRON / FERRO / PROTEINSUCCINYLATE	93615-44-2			2.9	Течно		
203238	KOLLIDON K-25/POLYVIDONE/	9003-39-8		2	5.3	таблетно		22,24,25
201014	LACTOSE MONOHYDRATE 100	64044-51-5		4.6	19.4	Таблетно,		
205737	LACTOSE MONOHYDRATE 200	64044-51-5		3.7	7.7	таблетно		
200110	LERBEK 0/CLOPIDOL 20% MET.BENZOQUATE1,67%	2971-90-6			1.0			
218723	LYCASIN 80/55 /MALTITOL/	9053-46-7		2.3	2	Течно		
209937	LYCATAB PGS/STARCH PREGELATINIZED/	9005-25-8		0.9	1.7	таблетно		
205796	MAGNESIUM STEARATE	557-04-0		2.2	4.8	Таблетно		
201626	MAYDIS AMYLUM/STARCH MAIZE/	9005-25-8		3.1	5.5	Таблетно		
218588	METHOCEL K15 M PREMIUM/HYPROMELLOSE/	9004-65-3		0.8	1.8	Таблетно		
215589	NATRIUM CHLORID VO TABLETI /ZA REGENER./	7647-14-5			12.7	таблетно, течно, масно, ампулно,	36	26,36
208809	NEUTRONYX S-60/RHODAPEX CO 436/			0.9	1.6	Течно		

[1] Во случај каде материјалот вклучува одреден број на посебни и достапни опасни супстанции, дадете детали за секоја супстанција
[1] Chemical Abstracts Service
[1] Закон за превоз на опасни материи (Сл. Лист на СФРЈ бр. 27/90, 45/90, Сл. Весник на РМ 12/93)
[1] Според Анекс 2 од Додатокот на Упатството

208094	PARACETAMOL	103-90-2	6.1		43	Таблетно, течно	22,36,37,38	26,36
217948	PENTOXIFYLLINE	6493-05-6		1.9	4.5	Таблетно, ампулно		
210242	POLYETHYLENE GLYCOL 1000	25322-68-3		1.5	4.7	Масно		
210285	POLYETHYLENE GLYCOL 400	25322-68-3		2.4	4	Масно, течно		
208787	POVIDONE IODINE	25655-41-8			4	Течно, масно		
205303	PRIMOJEL/SODIUM STARCH GLYCOLATE/	9063-38-1		1.3	3	Таблетно		
205265	PROPYLENE GLYCOL	57-55-6		1.8	8	Течно	36,38	26,36
208582	PROPYPHENAZONE	479-92-5			35	Таблетно		
206857	SACCHARUM ALBUM/SUCROSE/	57-50-1		4.6	11	Таблетно,		
205869	SORBITOL 70% /NON CRISTALLISING/	50-70-4		2.8	8.8	Течно		
207217	SUPPOCIRE A/FAT,HARD/	85665-33-4		0.4	0.8	масно		
206148	TALC	14807-96-6		1	1.6	Таблетно		
217263	VASELIN WHITE CD 806/150-170/WHITE PETR.			0.2	1.3	Масно		
210404	VERAPAMIL HYDROCHLORIDE	152-11-4		1.6	1.5	Таблетно, ампулно		
215988	VITAMIN C /ASCORBIC ACID DC-97 SF/	50-81-7		1.1	3.7	таблетно		

[1] Во случај каде материјалот вклучува одреден број на посебни и достапни опасни супстанции, дадете детали за секоја супстанција
[1] Chemical Abstracts Service
[1] Закон за превоз на опасни материи (Сл. Лист на СФРЈ бр. 27/90, 45/90, Сл. Весник на РМ 12/93)
[1] Според Анекс 2 од Додатокот на Упатството

ТАБЕЛА IV.1.1.2 Детали за суровини, меѓупроизводи, производи, итн. поврзани со процесите, а кои се употребуваат или создадени на локацијата за процес на водена екстракција

шифра	Материјал/ Супстанција[7]	CAS[5] Број	Категорија на опасност[8)]	Количина (тони)	Годишна употреба (тони)	Природа на употребата	R[6] - Фраза	S[12] -фраза
2000045	AMMONIA COMPRESSED	7664-41-7	8	2 ,3	14,5	Екстракција (во Фармација 1)	10-23-24-34-50	9-16-26-33-36-37-39-45-61
2000915	SODIUM HYDROXIDE TECHN. НАТРИУМ ХИДРОКСИД ТЕХН	1310-73-2	8	2,2	6,8	Екстракција (во Фармација 1)	36/38-35-34	26-45-37/39-24/25-29-36/37/39
2000327	CHARCOAL ACTIVATED ЈАГЛЕН МЕДИЦИНСКИ	16291-96-6	4.1	0	0,005	Прекристализација (во Фармација 2)	36/37-18-11	26-36
3000540	ACETIC ACID TECHN.	64-19-7	8	0	0,360	Прекристализација (во Фармација 2)	10-35	23-26-45
2000465	TARTARIC ACID TECHN.	87-69-4		0	0,370	Прекристализација (во Фармација 2)	36/37/38	26-36-37/39
2000475	HYDROCHLORIC ACID TECHN.	7647-01-0	8	0	10,2	Екстракција (во Фармација 1)	23-24-25-34-36-37-38	26-36-37-39-45
2000572	SULFURIC ACID TECHN.	7664-93-9	8	0	13,5	Екстракција (во Фармација 1)	36/38-35-39/23/24/25-23/24/25-11	26-30-45-36/37-16
2000575	CALCIUM HYDROXIDE TECHN. ХИДРИРАНА ВАР	1305-62-0	8	0	3	Екстракција (во Фармација 1)	41-34	26-39-45-36/37/39-27
2000577	АФИОНОВИ ШИШАРКИ			37,234	200 000	Екстракција (во Фармација 1)		
3000250	MORPHINE BASE	57-27-2				Прекристализација (во Фармација 2) Екстракција (во Фармација 1)	11-39/23/24/25	7-16-22-24/25-36/37-45-51

[5] Chemical Abstracts Service
[6] Според Анекс 2 од Додатокот на Упатството
[7] Во случај каде материјалот вклучува одреден број на посебни и достапни опасни супстанции, дадете детали за секоја супстанција
[8] Закон за превоз на опасни материи (Сл. Лист на СФРЈ бр. 27/90, 45/90, Сл. Весник на РМ 12/93)

ТАБЕЛА IV.1.2.1 Детали за суровини, меѓупроизводи, производи, итн. поврзани со процесите, а кои се употребуваат или создадени на локацијата

Реф. Бр или шифра	**Материјал/ Супстанција[1]**	**Мирис**			**Приоритетни супстанции[9]**			
		Миризливост Да/Не	Опис	Праг на осетливост µг/м^3				
258466	ALCOHOL	Да						
224014	ALCOHOL DEHYDRATED	Да						
213993	BHT /BUTYLHYDROXYTOLUENE/	Да						
210617	CIPROFLOXACINE HCL MONOHYDRATE	Да						
205117	CUTINA HR/CASTOR OIL HYDROGENATED/	Да						
213357	IRON / FERRO / PROTEINSUCCINYLATE	Да						
200110	LERBEK 0/CLOPIDOL 20% MET.BENZOQUATE1,67%	Да						
205796	MAGNESIUM STEARATE	Да						
208787	POVIDONE IODINE	Да						

Листа на приоритетни супстанции согласно Табелите III до VIII од Уредбата за класифицкација водите (Сл. Весник 18-99).

ТАБЕЛА IV.1.2.2 Детали за суровини, меѓупроизводи, производи, итн. поврзани со процесите, а кои се употребуваат или создадени на локацијата за процес Водена екстракција

Реф. Бр или шифра	**Материјал/ Супстанција**[1]	**Мирис**			**Приоритетни супстанции**[10]			
		Миризливост Да/Не	Опис	Праг на осетливост μг/м^3				
2000045	AMMONIA COMPRESSED	да						
2000915	SODIUM HYDROXIDE TECHN. НАТРИУМ ХИДРОКСИД ТЕХН	не						
2000327	CHARCOAL ACTIVATED ЈАГЛЕН МЕДИЦИНСКИ	не						
3000540	ACETIC ACID TECHN.	да						
2000465	TARTARIC ACID TECHN.	не						
2000475	HYDROCHLORIC ACID TECHN.	да						
2000572	SULFURIC ACID TECHN.	не						
2000575	CALCIUM HYDROXIDE TECHN. ХИДРИРАНА ВАР	не						
2000577	АФИОНОВИ ШИШАРКИ	не						
3000250	MORPHINE BASE	не						

[10] Листа на приоритетни супстанции согласно Табелите III до VIII од Уредбата за класифицкација водите (Сл. Весник 18-99).

Прилог 3 на ПОГЛАВЈЕ IV

ИНФОРМАЦИОНЕН ЛИСТ ЗА БЕЗОПАСНОСТ

ДДС №: BG836144932
ЕИК: 836144932

Дата на издание:	03.04.2007 г.
Издание:	3
Замена издание:	14.07.2006 г.
Стр.(брой)	8

АМОНЯК

1. Наименование на веществото и фирмата

1.1. Наименование на веществото: АМОНЯК, безводен

1.2. Употреба на веществото: В химическата промишленост, в хладилната техника и др.

Телефон за връзка в случай на спешност: За страната: Полиция -166 Пожарна охрана -160

2. Състав на веществото/препарата

2.1.

Показатели	Гранични стойности	CAS №	EINECS №	Опасност
Амоняк, %	мин. 99,90	7664-41-7	231-635-3	Да

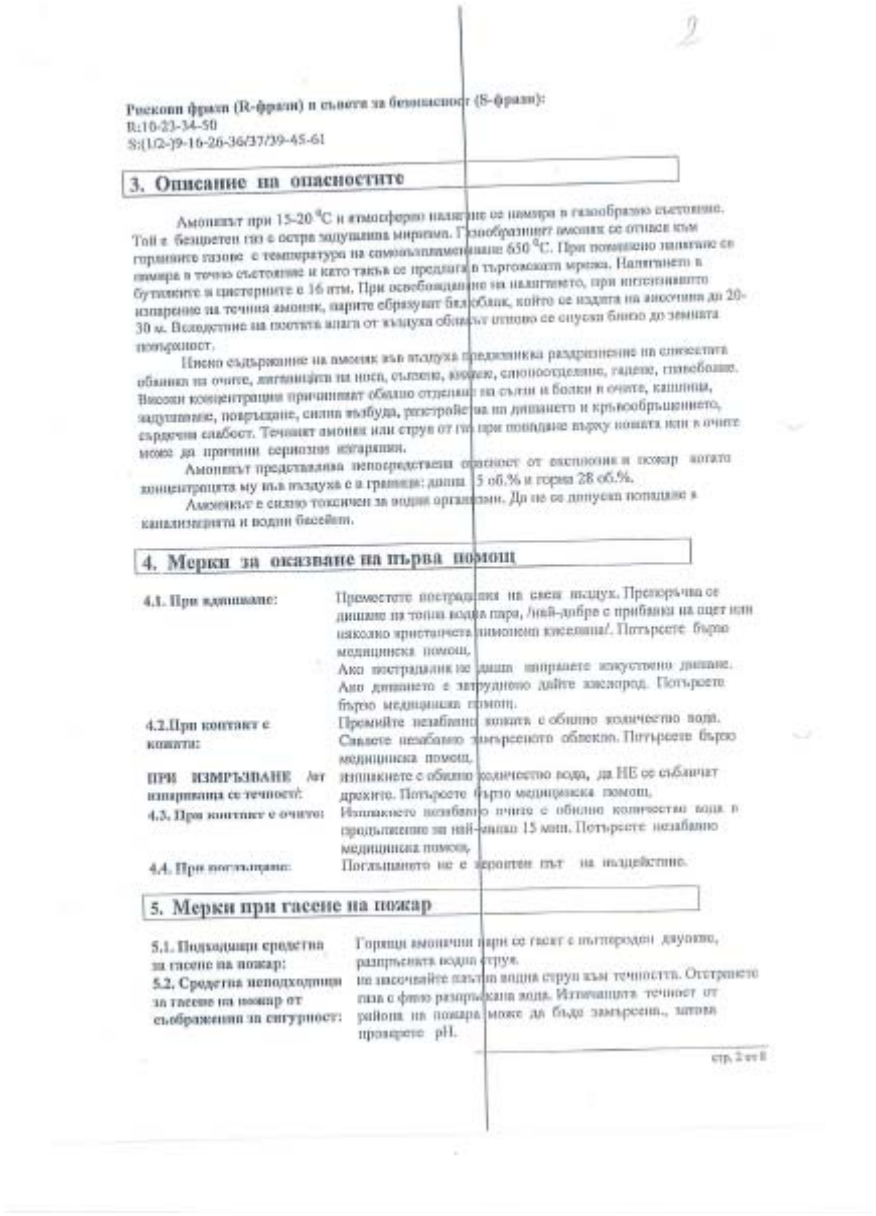
2.2. Класификация

Амонякът е класифициран като опасно химическо вещество съгласно Директива 67/548/ЕЕС.

Символи и знаци за опасност

T C N

токсичен корозивен опасен за околната среда



2

Ризични фрази (R-фрази) и совети за безбедност (S-фрази):
R:10-23-34-50
S:(1/2-)9-16-26-36/37/39-45-61

3. Описание на опасностите

Амонијакот при 15-20 °C и атмосферно налягање се намира в гасообразно състояние. Той е безцветен гас с остра задушлива миризма. Гасообразният амоняк се отвася към горивните газове с температура на самозапламеняване 650 °C. При повишено налягане се намира в течно състояние и като такъв се предлага в търговската мрежа. Налягането в бутилките и цистерните е 16 атм. При освобождаване на налягането, при интензивното изпарение на течния амоняк, парите образуват бял облак, който се издига на височина до 20-30 м. Вследствие на повтата влага от въздуха облакът отново се спуска ниско до земната повърхност.

Ниско съдържание на амоняк във въздуха предизвиква раздразнение на слизестата обвивка на очите, лигавиците на нос, гърло, кашлик, слюноотделяне, гадене, главоболие. Високи концентрации причиняват обилно отделяне на сълзи и болки в очите, кашлица, задушаване, повръщане, силна възбуда, разстройства на дишането и кръвообръщението, сърдечна слабост. Течният амоняк или струя от гас при попадане върху кожата или в очите може да причини сериозни изгаряния.

Амонякът представлява непосредствена опасност от експлозия и пожар когато концентрацията му във въздуха е в граници: долна 15 об.% и горна 28 об.%.

Амонякът е силно токсичен за водни организми. Да не се допуска попадане в канализацията и водни басейни.

4. Мерки за оказване на първа помощ

4.1. При вдишване: Преместете пострадалия на свеж въздух. Препоръчва се дишане на топла водна пара, /най-добре с прибавки на оцет или няколко кристалчета лимонена киселина/. Потърсете бързо медицинска помощ.
Ако пострадалият не диша направете изкуствено дишане. Ако дишането е затруднено дайте кислород. Потърсете бърза медицинска помощ.

4.2.При контакт с кожата: Премийте незабавно кожата с обилно количество вода. Свалете незабавно замърсеното облекло. Потърсете бърза медицинска помощ.

ПРИ ИЗМРЪЗВАНЕ Ако изпарения се течност: изплакнете с обилно количество вода, да НЕ се събличат дрехите. Потърсете бързо медицинска помощ.

4.3. При контакт с очите: Изплакнете незабавно очите с обилно количество вода в продължение на най-малко 15 мин. Потърсете незабавно медицинска помощ.

4.4. При поглъщане: Поглъщането не е вероятен път на въздействие.

5. Мерки при гасене на пожар

5.1. Подходящи средства за гасене на пожар: Горящи амоячни пари се гасят с разпределен двуокис, разпръснати водни струи.

5.2. Средства неподходящи за гасене на пожар от съображения за сигурност: Не насочвайте плътни водни струи към течността. Отстранете газ с фино разпръсната вода. Изтичащата течност от района на пожара може да бъде замърсена., затова проверете pH.

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5.3. Специфични опасности, свързани с експозицията на веществото и произтичащи от него продукти на изгарянето и отделящи се газове:	Евакуирайте от района цените околни, незает с гасенето на пожара. Ако е възможно спрете изтичането на амоняк, след това гасете огъня според видовете материали, които горят. Ако е възможно преместете от района съдовете пълни с амоняк. Поддържайте съдовете охладени чрез пръскане с голямо количество вода. Опасни продукти от горенето са изтощ описи.
5.4. Специални предпазни средства за пожарникарите:	Специални устойчиви на високи температури облекло, ръкавици, ботуши [EN 469, CE], и задължително изолиращ дихателен апарат напр.тип Сигурн, Дрегер.

6. Мерки при аварийно изпускане

6.1. Лични предпазни мерки:	Изведете незабавно персонала, незает с отстраняване на аварията от района. Елиминирайте всички възможни източници на запалване и осигурете максимална вентилация, устойчива на експлозия. Затворете източника на изтичане ако е възможно. Изолирайте всяка бутилка, от който има изтичане. В зависимост от големината на изпускане оперативно да се прецени необходимостта от широката на опасността. Личните предпазни средства които трябва да се използуват и използват са: филтриращ противогаз тип "М", защитни очила и облекло, гумени ръкавици и гумени ботуши. При изпускане на големи количества да се използват пълни защитни костюми и изолиращи противогази. Нивата на амоняк трябва да бъдат под пределните норми, въздухът трябва да съдържа най-малко 19 % кислород преди персоналът да бъде допуснат отново в района.
6.2. Мерки за опазване на околната среда:	Аварийните води могат да се контролират с водна струя, но изтичащата вода може да се замърси и замърси и околната среда. Контролирайте нейното pH.
6.3. Средства за почистване:	Малки количества амоняк могат да се разредят с вода. Получеият разтвор от амониев хидроксие може да се неутрализира и получения безопасен продукт трябва да се изхвърли в съответствие с правилата.

7. Работа с веществото и съхранение

7.1. Работа с веществото:	Не капете, не търкаляйте, не плъзгайте и не изпускайте бутилките. Използвайте подходяща ръчна количка, предназначена за преместване на бутилката. Никога не се опитвайте да вдигате бутилката, като я държите за капачката. При употреба винаги закрепвайте бутилките. Използвайте регулятор за намаляване на налягането или отделен контролен кранан за безопасно изпускане на газ от бутилката. Използвайте възвратен клапан, за да предотвратите връщане на газ в цилиндъра. Никога не прилагайте пламък или локализирано нагряване директно върху която и да е част от бутилката. Не позволявайте нито една част от бутилката да се нагрява над 40°. Никога

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не поставяйте предмети (напр. гаечен ключ, отвертка и др.) в отворите на капачката на клапана. Това може да повреди клапана и да причини изтичане. Всички системи от тръби и съединените с тях съоръжения трябва да бъдат заземени. Електрическите съоръжения трябва да не образуват искри или да бъдат обезопасена против експлозия.

7.2. Съхранение: Съхранявайте съдовете в сухо, хладно, добре вентилирано безопасно помещение, защитени от пряка слънчева светлина. Бутилките трябва да се съхраняват във вертикално положение с поставени уплътнения на отвори на клапани и капачки за предпазване на клапаните. Не трябва да има източници на запалване. Бутилките с амоняк не трябва да се съхраняват близо до киселини или газове, образуващи киселини. В районите на съхранение и употреба трябва да се поставят табели с надпис: "Забранено пушенето и пушенето на огън". Пълните и празните съдове трябва да се съхраняват отделно.

8. Контрол при експозиция и лични предпазни средства

8.1. Граници на експозиция: Съгласно Наредба № 13/30.12.2003 год. за пределно допустимите концентрации на вредните вещества във въздуха на работната среда, гранична стойност на амоняк във въздуха на работната среда е:

8 часа	14 мг/м^3
15 минути	36 мг/м^3

8.2.Контрол на експозиция: Да се осигури херметичност на цялата инсталация, в която се използва амоняк - връзки, апарати, тръбопроводи; да се използват подходящи КИП, сигнализации и блокировки; да се отстраняват своевременно пропуските; да не се допуска работа при неизправни машини, съоръжения, ел.мрежа. Да се спазват условията на транспорт, съхранение, работа. Да се отчитат специфичните условия на употреба при клиента.

8.2.1. Контрол при експозиция в работна среда: Да се осигури подходяща естествена и/или принудителна вентилация, за да се поддържа концентрацията на амоняк под допустимата граница на въздействие.

8.2.1.1. Защита на дихателните пътища: Филтриращ противогаз: да се използва при съдържание на кислород във въздуха най-малко19 %,

- тип "М"(черен) - универсален. Време на защитно действие – 90 мин.;
- тип 620 St A - ДРЕГЕР. Време на защитно действие - 120 мин.

В районите с изпускане на големи количества газ или в случаите, когато концентрацията не е известна, трябва да се използва изолиращ дихателен апарат - шлангов или кислородизолиращ тип напр. ПШ-1, ПШ-2, ДРЕГЕР.

8.2.1.2. Защита на ръцете: Да се носят гумени или неопренови ръкавици.

8.2.1.3. Защита на очите: Защитни очила за работа. Лицев щитек или защитни очила в комбинация с дихателна маска.

5

8.2.1.4. Защита на кожата и тялото: Да се носят ботуши и горно работно облекло, устойчиво на химикали.
В райони с изпускане на големи количества или когато концентрациите на амоняк във въздуха не са известни да се използва пълен изолиращ костюм напр. тип Дрегер, задължително с изолиращ противогаз.

8.2.2. Контрол на въздействието на веществото върху околната среда:

ДРУГА ЗАЩИТНА ЕКИПИРОВКА: При работа с бутилки: кожени ръкавици с пет пръста за предпазване от охлуждане, предпазни обувки.

ВНИМАНИЕ: Трябва да се поддържат в готовност душ и фонтан за измиване на очите. Контактът на ръкавиците или облеклото със студено изпаряваща се течност може да причини криогенни изгаряния или премръзване.

9. Физични и химични свойства

9.1. Обща информация	
Външен вид, мирис, агрегатно състояние:	Безцветен газ с остър, силен мирис, който се открива лесно; граница на възприемане по миризмата 0,037 мг/л
9.2. По-важна информация, свързана с човешкото здраве, безопасността и околната среда:	
Молекулно тегло:	17.0
PH на 1%-ен воден разтвор:	11
Специфично тегло:	(въздух = 1):0.59
Относителна плътност:	(вода = 1):0.7 при -33 °C
Точка на замръзване / Точка на топене:	-77.7 °C
Температура на кипене:	- 33°C
Температура на самозапалване:	651°C
Граници на експлозивност във въздуха:	15 – 28 об.%
Парен натиск:	при 26 °C: 1013 хПа
Разтворимост във вода гр/100 мл при 20 °C:	54 гр

Водния разтвор лесно отделя газообразен амоняк

10. Стабилност и реактивоспособност

ХИМИЧНА СТАБИЛНОСТ: Стабилен

10.1. Условия, които трябва да се избягват Високи температури. Бутилките не трябва да се излагат на температури, надвишаващи 40°C.
Чувствителни на удар смеси се образуват с живачни, сребърни и златни окиси.

MSDS Number: **C2046** * * * * * *Effective Date:* ***11/21/08*** * * * * * *Supercedes:* ***01/13/06***

MSDS Material Safety Data Sheet

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865

Mallinckrodt CHEMICALS | J.T.Baker

24 Hour Emergency Telephone: 908-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

CHARCOAL ACTIVATED

1. Product Identification

Synonyms: Activated carbon; Charcoal, activated, powder; carbon black; Carboraffin; Carborafine
CAS No.: 7440-44-0
Molecular Weight: 12.01
Chemical Formula: C
Product Codes:
J.T. Baker: 1560
Mallinckrodt: 4394

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Steam Activated Carbon	7440-44-0	90 - 100%	Yes

3. Hazards Identification

Emergency Overview

CAUTION! ACTIVATED CARBON AFFECTS THE RESPIRATORY AND CARDIOVASCULAR SYSTEMS.

SAF-T-DATA(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate
Flammability Rating: 1 - Slight
Reactivity Rating: 1 - Slight
Contact Rating: 1 - Slight
Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES
Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:
No adverse effects expected. May cause mild irritation to the respiratory tract.
Ingestion:
No adverse effects expected. May cause mild irritation to the gastrointestinal tract.
Skin Contact:
Not expected to be a health hazard from skin exposure. May cause mild irritation and redness.
Eye Contact:
No adverse effects expected. May cause mild irritation, possible reddening.
Chronic Exposure:
Prolonged inhalation of excessive dust may produce pulmonary disorders.
Aggravation of Pre-existing Conditions:
No information found.

4. First Aid Measures

Inhalation:
Remove to fresh air. Get medical attention for any breathing difficulty.
Ingestion:
Give several glasses of water to drink to dilute. If large amounts were swallowed, get medical advice.
Skin Contact:
Not expected to require first aid measures. Wash exposed area with soap and water. Get medical advice if irritation develops.
Eye Contact:
Wash thoroughly with running water. Get medical advice if irritation develops.

5. Fire Fighting Measures

Fire:
As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. Activated carbon is difficult to ignite and tends to burn slowly (smolder) without producing smoke or flame. Wet activated carbon depletes oxygen from the air. Materials allowed to smolder for long periods in enclosed spaces, may produce amounts of carbon monoxide which may reach the lower explosive limit for carbon monoxide of 12.5% in air. Contact with strong oxidizers such as ozone or liquid oxygen may cause rapid combustion.
Explosion:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Minimum explosible concentration 0.140 g/l.
Fire Extinguishing Media:
Water spray, dry chemical, alcohol foam, or carbon dioxide.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Clean up spills in a manner that does not disperse dust into the air. Use non-sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Pick up spill for recovery or disposal and place in a closed container. Warning! Spent product may have absorbed hazardous materials.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Keep away from moisture and oxidizers. Avoid dust dispersal.
Wet activated carbon depletes oxygen from the air and therefore dangerously low levels of oxygen may be encountered in confined spaces. Work procedures for potentially low oxygen areas should be followed.
Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
- OSHA Permissible Exposure Limits (PELs):
activated carbon (graphite, synthetic): total particulate = 15 mg/m3 (TWA), respirable fraction = 5 mg/m3 (TWA).
- ACGIH Threshold Limit Values (TLVs):
graphite, all forms except graphite fibers: 2 mg/m3 (TWA).

Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):
For conditions of use where exposure to the dust or mist is apparent, a half-face dust/mist respirator may be worn. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:
Wear protective gloves and clean body-covering clothing.

Eye Protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:
Fine black powder.

Odor:
Odorless.

Solubility:
Insoluble in water.

Specific Gravity:
1.8 - 2.1

pH:
5.0-10.0

% Volatiles by volume @ 21C (70F):
0

Boiling Point:
Sublimes.
Melting Point:
3550C (6422F)
Vapor Density (Air=1):
0.4
Vapor Pressure (mm Hg):
1 @ 3586C (6487F)
Evaporation Rate (BuAc=1):
No information found.

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
Involvement in a fire causes formation of carbon dioxide and carbon monoxide.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Strong oxidizers such as ozone, liquid oxygen, chlorine, permanganate, etc. may result in rapid combustion. Avoid contact with strong acids.
Conditions to Avoid:
Moisture and incompatibles.

11. Toxicological Information

Investigated as a reproductive effector.

--------\Cancer Lists\----------

Ingredient	---NTP Carcinogen--- Known	Anticipated	IARC Category
Steam Activated Carbon (7440-44-0)	No	No	None

12. Ecological Information

Environmental Fate:
No information found.
Environmental Toxicity:
No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

--------\Chemical Inventory Status - Part 1\----------

Ingredient	TSCA	EC	Japan	Australia
Steam Activated Carbon (7440-44-0)	Yes	Yes	No	Yes

--------\Chemical Inventory Status - Part 2\----------

Ingredient	Korea	--Canada-- DSL	NDSL	Phil.
Steam Activated Carbon (7440-44-0)	Yes	Yes	No	Yes

--------\Federal, State & International Regulations - Part 1\----------

Ingredient	-SARA 302- RQ	TPQ	------SARA 313--- List	Chemical Catg.
Steam Activated Carbon (7440-44-0)	No	No	No	No

--------\Federal, State & International Regulations - Part 2\----------

Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
Steam Activated Carbon (7440-44-0)	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.
Poison Schedule: None allocated.
WHMIS:
This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **0** Flammability: **1** Reactivity: **0**
Label Hazard Warning:
CAUTION! ACTIVATED CARBON AFFECTS THE RESPIRATORY AND CARDIOVASCULAR SYSTEMS.
Label Precautions:
Avoid contact with eyes, skin and clothing.
Avoid breathing dust.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.

Label First Aid:
If inhaled, remove to fresh air. Get medical attention for any breathing difficulty.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****
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Phone Number: (314) 654-1600 (U.S.A.)

BRENNTAG

ISO 11014-1:1994

SIGURNOSNO-TEHNIČKI LIST ZA HEMIJSKE PROIZVODE

Naziv proizvoda	SIRĆETNA KISELINA TG 80%D220KG	Datum:	4.11.2010.
Namena proizvoda	Hemijski intermedijator	Izdanje:	15.3.2010.

1. IDENTIFIKACIJA PROIZVODA I PROIZVOĐAČA/UVOZNIKA

- **Naziv proizvoda:** SIRĆETNA KISELINA TG 80%D220KG
- **Proizvođač:** Brenntag CEE GmbH
  Linke Wienzelle 152
  AT 1060 Wien

- **Informacije o proizvodu/opasnostima/upotrebi:** 011-32-93-886 radni dan 09.00-15.00 h
- **Služba za vanredna stanja:** Nacionalni centar za kontrolu trovanja-VMA-011-3609-040

2. SASTAV/PODACI O SASTOJCIMA

- **Hemikalija:** ☐ **Proizvod** ☒
- **Hemijski naziv Hemikalije:**

- **CAS broj:** /
- **Hemijski sastav proizvoda (koncentracija / opseg koncentracije):**

- **Sastojci koji pridonose opasnosti proizvoda:**

Aktivne komponente:	%	CAS broj	Oznaka opasnosti	Oznaka upozorenja	Oznaka obaveštenja
Sirćetna kiselina	80.00	64-19-7	C	R10, R35	

3. IDENTIFIKACIJA OPASNOSTI

- Najvažnije opasnosti i efekti proizvoda: Klasifikovan je kao opasan.
  na zdravlje ljudi: Klasifikovan je kao opasan.
  na životnu okolinu: Klasifikovan je kao opasan.
  fizičko hemijske opasnosti: /
- **Posebne opasnosti:**
- **Glavni simptomi delovanja na zdravlje ljudi:**
  Udisanje: /
  Koža: Izaziva opekotine.
  Oči: Izaziva opekotine.

Naziv proizvoda:	SIRĆETNA KISELINA TG 80%D220KG	Datum:	4.11.2010.
		Izdanje:	15.3.2010.

Gutanje: Izaziva opekotine.

- **Pregled posebnih stanja:** Ne postoje

4. MERE PRVE POMOĆI

- **Mere za pružanje prve pomoći:**

nakon udisanja:	Izvesti osobu na čist vazduh. Ukoliko je potrebno priključiti na veštačko disanje i potražiti savet lekara.
nakon dodira s kožom:	Oprati mesto kontakta sapunom i vodom, skinuti zaprljanu odeću i obuću. Odmah potražiti savet lekara.
nakon dodira s očima:	Odmah oprati ruke, prstima raširiti kapak i ispirati oko pod mlazom vode 15-ak minuta. Odmah potražiti pomoć lekara.
nakon gutanja:	Isprati usta vodom, zatim popiti veliku količinu vode. Ne izazivati povraćanje. Odmah potražiti pomoć lekara. Dežurna služba Hitne medicinske pomoći telefon 94

- **Napomena za osobu koja pruža prvu pomoć/doktora:** Lečenje treba biti simptomatsko i usmereno na olakšanje tegoba.

5. MERE ZA SUZBIJANJE POŽARA

- **Sredstva za gašenje požara:**

PRIKLADNA:	Vodena magla, pena, prah, CO_2
NE SME SE UPOTREBLJAVATI:	Vodeni mlaz

- **Protivpožarne mere za posebne opasnosti:** Nema podatka.
- **Posebne metode za gašenje požara:** -
- **Posebna oprema za zaštitu vatrogasaca:** Vatrogasci moraju nositi samostalni uređaj za disanje i odeću otpornu na toplotu.

6. MERE KOD SLUČAJNOG ISPUŠTANJA

- **Lične mere opreza:** Upotrebiti zaštitnu opremu (tačka 8). Evakuisati nezaposlene radnike i one koji nemaju zaštitnu opremu. Slediti protivpožarne instrukcije (tačka 5).
- **Mere zaštite životne sredine:** Spreciti isticanje i izlivanje u vodotokove,kanalizaciju i drenažne sisteme postavljanjem peščanih brana i pregrada. Omogućiti dobro provetravanje. U slučaju isticanja veće količine obavestiti nadležne organe i ekološku inspekciju.

- **Način čišćenja i sakupljanja:** Kod malih isticanja, proizvod prekriti peskom, zemljom ili drugim adsorpcionim materijalom, pokupiti lopatom, i odložiti u burad za odlaganje koja se mogu hermetički zatvoriti. Pri većim izlivanjima, ograditi prolivenu materijal fizičkim barijerama (ograda, zemljane brane) da ne dođe u vodotokove, i što pre, da se ne upije u zemlju, pokupiti adekvatnom pumpom i pretočiti u praznu cisternu. Pozvati ekološku inspekciju i predati dokumentaciju i otpad na čuvanje pravnim licima ovlašćenim od strane ministarstva nadležnog za zaštitu životne sredine.
- **Dodatna upozorenja:** Kod nesreće pri transportu, propisno uzemljiti cisternu, označiti mesto nesreće i pozvati odgovorne osobe uvoznika i stručne službe za zbrinjavanje posledica nesreće. MUP RS tel 92

7. RUKOVANJE I SKLADIŠTENJE

- **Rukovanje: Uobičajene mere predostrožnosti kada se rukuje sa hemikalijama.**

mere opreza: Osigurati dobro provetravanje. Izbegavati oksidanse. Držati dalje od izvora toplote i otvorenog plamena. Dobro prati ruke nakon rukovanja.

saveti za sigurno rukovanje: Ne udisati pare, izbegavati dodir s kožom i očima.

- **Skladištenje:** tehničke mere i uslovi skladištenja:

PRIKLADNI: Skladištiti u dobro zatvorenim sudovima, u hladnom i dobro provetrenom prostoru na temperaturi od 17 do 25° C

IZBEGAVATI: /

- **Ambalažni materijali:**

PREPORUČENI: Originalna ambalaža proizvođača.

NEPRIKLADNI: Nije dopušteno pretakanje u bilo kakve druge vrste ambalaže.

8. KONTROLA IZLOZENOSTI/LIČNA ZAŠTITA

- **Tehničke mere za smanjenje izloženosti:** Osigurati prikladno provetravanje radnog prostora.
- **Parametri kontrole:**

Naziv opasne materije	MDK max dozvoljena koncentracija ppm (m/v)	Biološke granične vrednosti
Sirćetna kiselina	MAK: 25 mg/m³, 10 ppm, (AT) MAK CEIL: 50 mg/m³, 20 ppm, TWA: 25 mg/m³, 10 ppm,	8x5 minuta/smeni

- **Lična zaštitna sredstva za:**

zaštitu disajnih organa: Maska.

zaštitu ruku: U slučaju produženog i ponovljenog dodira: nitrilne rukavice. Redovno vršiti pregled mogućih oštećenja.

zaštitu očiju: Zaštitne naočare s bočnim štitnicima.

Naziv proizvoda: **SIRĆETNA KISELINA TG 80%D220KG** Datum: 4.11.2010.
Izdanje: 15.3.2010.

zaštitu kože i tela — Radna obuca i odeca. Pamučne ili poliesterske kecelje. Pri riziku od direktnog kontakta nositi kecelju otpornu na hemikalije i/ili odelo i čizme od nepropusnog materijala.

- **Posebne higijenske mere i mere opreza:** Nakon rukovanja, a pre jela i pušenja, oprati ruke do laktova i lice. Isto se odnosi na kraj radnog dana.

9 FIZIČKA I HEMIJSKA SVOJSTVA

- Fizičko stanje		
- Oblik		Tečnost
- Boja		Bezbojna
- Miris:		ostar
- pH vrednost (pri konc. i temp):	20 °C	<2
- Temp ključanja/područje ključanja:	°C	104
- Tačka tečenja/mrznjenja:	°C	/
- Temperatura gorenja	°C	550
- Tačka paljenja:	°C	75
- Temperatura samozapaljenja:	°C	/
- Granica eksplozivnosti:	vol. %	Moguce je stvaranje eksplozivnih smesa para/vazduh Donja granica: 4 %(V) Gornja granica : 17 %(V)
- Napon pare, 20 °C	mbar	20
- Gustina pare:	kg/m³	nema podataka
- Gustina	g/cm³	1.071
- Rastvorljivost :	g/L	Rastvorljiv u vodi
- Rastvorljivost u alkoholu:		/
- Particioni koeficijent:n-oktanol/voda		/
-Viskoznost, dinamička, na 20°C:	mPa-s	/
-Viskoznost-kinematička,	mm²/s	/
-Index viskoznosti		

10. STABILNOST

- Stabilnost:	Stabilan pri pravilnoj upotrebi.
- Uslovi koje treba izbegavati:	Izbegavati toplotu, otvorene izvore paljenja, vlagu. Proizvod je higroskopan.
- Materijali koje treba izbegavati:	Oksidaciona sredstva, kiseline, baze, alkohole, lake metale, azotnu kiselinu.

- **Opasni proizvodi razlaganja:** Zapaljive pare
- **Namena proizvoda:** Hemijski intermedijator
- **Ne sme se upotrebljavati za:** U bilo koje druge svrhe

11. PODACI O TOKSIČNOSTI

- **Akutno trovanje:**
  - oralno (LD_{50}) 3.310 mg/kg
  - inhalacijsko (LD_{50}) 40 mg/l 4 h
  - dermalno (LD_{50}) 1.060 mg/kg
- **Lokalni učinci:**

koža	Korozivno deluje na kožu.
oči	Korozivno deluje na oči, može dovesti do ozbiljnog oštećenja očiju.
organi za varenje	Ukoliko se proguta može izazvati jake opekotine usta, grla, perforaciju jednjaka i želudca.
organi za disanje	/

- **Hronično trovanje ili dugotrajno izlaganje:** /
- **Efekat izlaganja**
  - Jednokratno: Nema podatka.
  - Višekratno: Nema podatka.
  - Dugotrajno: Nema podatka.
- **Trenutni efekti:** Nema podatka.
- **Naknadni efekti:** Nema podatka.
- **Posebni efekti (karcinogenost, mutagenost, reproduktivnost):** Nema poznatih štetnih uticaja.
- **Dopunski efekti:** /

12. EKOLOŠKI PODACI

- **Pokretljivost:**	Metoda:
poznata ili predviđena raspodela u prostoru	Nema podatka.
površinski napon	Nema podatka.
apsorpcija/desorpcija	Nema podatka.
ostala fizičko-hemijska svojstva (vidi odeljak 9)	Rastvorljiv u vodi.

- **Postojanost/razgradljivost:**

biotička ili abiotička razgradnja	Nema podatka.
razgradnja uz prisustvo vazduha/ bez njega	Nema podatka.
postojanost	**Biorazgradljiv**

- **Bioakumulacija:**

bioakumulacijski potencijal Ne očekuje se akumulacija putem lanca ishrane.
biopovećanje Nema podatka.

- **Efekti proizvoda na životnu sredinu:**

na vodu Štetan
na vazduh /
na tlo /

- **Ekotoksičnost:**

za vodene organizme Štetan.
za organizme u tlu Nema podatka.
za biljke i kopnene životinje Nema podatka.

- **Ostali podaci:**

13. POSTUPANJE S OTPADOM

- **Način postupanja s otpadom:**

Ostaci od proizvoda: Izbegavati da proliveni proizvod dođe u kontakt s tlom i površinskim vodotokovima. Ostatke proizvoda predati ovlašćenom pravnom licu za sakupljanje opasnog otpada.

Korišćena ambalaža: Postupiti prema važećim propisima.

- **Važeći propisi u RS:** Pravilnik o načinu postupanja sa otpacima koji imaju svojstvo opasnih materija (Sl.glasnik RS 12/95), Zakon o postupanju sa otpadnim materijama (Sl.glasnik RS 25/96, 26/96)

14. PODACI O TRANSPORTU

- **Klasifikacione oznake za prevoz:**

kopneni:	vodeni: /	pomorski:	vazdušni:
Klasa 8, Grupa II, Klasif. kod C3, Nalepnica 8, Br. rizika 80		Klasa 8, Grupa II, Nalepnica 8, EmS F-A, S-B	

- **UN klasifikacioni broj:** 2790
- **Dodatni propisi:** Zakon o prevozu opasnih materija (Sl.list SFRJ 27/90,45/90,24/94,28/96,21/99,44/99), Uredba o prevozu opasnih materija u drumskom i železničkom saobraćaju (Sl.glasnik RS 53/02)
- **Nalepnica**

Naziv proizvoda:	SIRĆETNA KISELINA TG 80%D220KG	Datum:	4.11.2010.
		Izdanje:	15.3.2010.

15. PODACI O PROPISIMA

- Vazeći propisi: Zakon o hemikalijama (Sl glasnik RS 25/09),Lista otrova razvrstanih u grupe (Sl list SRJ 12/00), Zakon o zaštiti životne sredine (Sl glasnik RS 135/04), Zakon o zaštiti potrošača (Sl glasnik RS 79/05),

- Podaci o opasnosti i merama sigurnosti (prema nalepnici):

Oznaka opasnosti: C-Korozivno dejstvo

Oznake upozorenja R:
R34- Izaziva opekotine.

Oznake obaveštenja S:
S23- Ne udisati pare proizvoda.
S26- U slučaju kontakta sa očima, isprati velikom količinom vode i potražiti pomoć lekara.
S45- U slučaju nesreće ili ako se ne osećate dobro, odmah potražite savet lekara i pokažite STL.

16. OSTALI PODACI

R10-Zapaljiv.
R35- Izaziva jake opekotine.

Svi podaci iz ovog STL-a zasnivaju se na sadašnjim znanjima i ne garantuju određene osobine. Informacije prikazane u ovom STL-u su korigovane u odnosu na najnovija saznanja i informacije na dan štampanja. Informacije su predviđene samo kao vodič za sigurno rukovanje, korišćenje, obradu, skladištenje, transport i odlaganje i ne sme se smatrati garancijom ili specifikacijom kvaliteta. Informacija se odnosi samo na označene specifične supstance i ne važi za iste supstance ukoliko se kombinuju sa drugim materijalima ili koriste u bilo kom drugom procesu, ukoliko to nije naznačeno u tekstu.
Ovaj STL sarži informacije vezane isključivo za sigurnost i ne može zameniti informacije o tehničkim karakteristikama proizvoda.

Safety data for l-tartaric acid

Click here for data on tartaric acid in student-friendly format, from the HSci project

Glossary of terms on this data sheet.

The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers.

General

Synonyms: 2,3-dihydroxybutanedioic acid, dextrotartaric acid, 2,3-dihydrosuccinic acid, 1,2-dihydroxyethane-1,2-dicarboxylic acid, (+)-tartaric acid, (R,R)-(+)-tartatic acid, 3-hydroxymalic acid
Use: cooking, brewing
Molecular formula: $C_4H_6O_6$
CAS No: 87-69-4
EC No: 201-766-0

Physical data

Appearance: white crystals
Melting point: 170 - 172 C
Boiling point:
Vapour density: 5.18 g/l
Vapour pressure:
Specific gravity:
Flash point: 150 C
Explosion limits:
Autoignition temperature: 797 F

Stability

Stable. Incompatible with oxidizing agents, bases, reducing agents. Combustible.

Toxicology

May be harmful by inhalation, ingestion or skin absorption. Irritant.

Toxicity data

(The meaning of any abbreviations which appear in this section is given here.)
IVN-MUS LD50 485 mg kg^{-1}

Risk phrases

(The meaning of any risk phrases which appear in this section is given here.)
R36 R37 R38.

Transport information

Non-hazardous for air, sea and road freight.

Personal protection

Minimize contact.

Safety phrases

(The meaning of any safety phrases which appear in this section is given here.)
S26 S36.

OLTCHIM

SAFETY DATA SHEET
Prepared in accordance with Annex II of the REACH regulation EC 19007/2006, Regulation (EC) 1272/2010 and Regulation 453/2010

SOLID SODIUM HYDROXIDE FLAKES /PRILLS/BLOCK)

Revision: 0 Last up date: Date issued: November 15, 2010 pag.1/30

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name	Sodium hydroxide flakes/prills/block
IUPAC name	Sodium Hydroxide
Synonym	Caustic soda
EC#	215-185-5
CAS #	1310-73-2
Nr. Index	011-002-00-6
Molecular Formula	NaOH
Molecular weight	40.01
REACH Registration number	01-2119457892-27-0065
Chemical characterization	Inorganic mono constituent substance

1.2. Relevant identified uses of the substance or mixture and uses advised against

Table 1: Identified uses

Identified use / IU number	Sector of End Use (SU)	Preparation Category (PC)	Process category (PROC)	Environmental Release Category (ERC)	Article category (AC)	Exposure Scenario
1	SU 1-24 except 21, 22	Not applicable	PROC 1-4, 8-9	ERC 1	Not applicable	ES 1: Manufacturing of liquid NaOH
2	SU 1-24 except 21, 22	Not applicable	PROC 1-4, 8-9	ERC 1	Not applicable	ES 2: Manufacturing of solid NaOH
3	SU 1-24 except 21, 22	PC 0-40	PROC 1-27	ERC 1-7, 12	Not applicable	ES 3: Industrial and professional use of NaOH
4	SU 1-24 except 21, 22	PC 0-40	PROC 1-27	ERC 2, 3, 8-11	Not applicable	
5	SU 21	PC 0-40	Not applicable	ERC 8-11	Not applicable	ES 4: Consumer use of NaOH

Елаборат од: Технички Девелопмент Департмент

Uses advise against: There are no uses advised against.

1.3. Details of the supplier of the safety data sheet

Name	S.C. OLTCHIM S.A
Address	1 Uzinei Street, 240050 Rammicu Valcea, Romania
Phone №	+40 250 701 200
FAX №	+40 250 735 030
E-mail of competent person responsible for SDS in the MS or in the EU:	tehnic@oltchim.ro

1.4 Telefon de urgenta

European Emergency N°:	112
Emergency telephone at the company:	+40/250/738141
Available outside office hours:	24h/zi/365zile

2. HAZARDS IDENTIFICATION

2.1Classification of the substance
2.1.1.Classification according to Regulation (EC) 1272/2008

Classification	Hazard statement:
Skin corrosive; category 1A	H314: Causes severe skin burns and eye damage
Corrosive to metals; category 1	H290: May be corrosive to metals

2.1.2 Classification according to Directive 67/548/EEC

Classification	C – corrosive
R-phrases	R35 - causes severe burns

2.1.3 Additional information

Risk advice to man and the environment
Sodium hydroxide causes severe burns of the eyes, even blindness. In skin contact can cause severe burns. Sodium hydroxide may be fatal if swallowed. Breathing the dust can irritate the mouth, nose and throat. Exposure to high levels may irritate the lungs, causing coughing and/or shortness of breath. Still higher exposure can cause a build up of fluid in the lungs (pulmonary edema).
In contact with water generates large amounts of heat. The high water solubility indicate that NaOH will be found predominantly in water. Significant emissions or exposure to the terrestrial environment and to the air are not expected either. The aquatic effect is due to possible pH changes related to OH^- discharges, as the toxicity of the Na^+ ion is expected to be insignificant compared to the (potential) pH effect.

2.2. Label elements
2.2.1. Labeling according to Regulation (EC) 1272/2008

Signal word:	Warning
Hazard Pictogram Codes and Symbols:	 GHS05: corrosion
Hazard statements:	H314: Causes severe skin burns and eye damage H290: May be corrosive to metals

Specific concentration limits

Skin Corr. 1A; H314	$C \geq 5\ \%$
Skin Corr. 1B; H314	$2\ \% \leq C < 5\ \%$
Skin Irrit. 2; H315	$0{,}5\ \% \leq C < 2\ \%$
Eye Irrit. 2; H319	$0{,}5\ \% \leq C < 2\ \%$

Precautionary statements

P260:	Do not breathe dust/fume/gas/mist/vapours/spray.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P303 + P361 + P353:	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305 + P351 + P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310:	Immediately call a POISON CENTER or doctor/physician.

2.2.2. **Labeling according to Directive 67/548/EEC**

Indication of danger: C – corrosive

R-phrase: R35 - causes severe burns

S-phrases:
(S1/2 - keep locked up and out of reach of children)
S26 - in case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S37/39 - wear suitable gloves and eye/face protection
S45 - in case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Specific concentration limits:

C; R35 (Corrosive; Causes severe burns):	$C \geq 5\ \%$
C; R34 (Corrosive; Causes burns):	$2\ \% \leq C < 5\ \%$
Xi; R36/38 (Irritant; Irritating to eyes and skin):	$0{,}5\ \% \leq C < 2\ \%$

2.3. **Other hazards**

The substance does not meet the criteria for PBT or vPvB substance.
No other hazards identified.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	PBT/ vPvB	CAS no/EC No/REACH No.	Classification according to Reg (EC) No. 1272/2008)	Classification according to D 67/548/EC	Concentration ,% (w/w)
Sodium Hydroxide	No/No	1310-73-2 215-185-5 01-2119457892-27-0065	Skin corr, cat 1A; H314 Met Corr, cat 1A; H290	C: R35	Min.98%

Impurities
No impurities relevant for classification and labelling.

4. FIRST - AID MEASURES

4.1 Description of first aid measures

General Advice: IF exposed or if you feel unwell: Call a Poison Center or doctor/physician. Show this safety data sheet to the doctor in attendance.
If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Apply artificial respiration if the person has stopped breathing and provide oxygen if breathing is difficult.
In case of skin contact: Remove/Take off immediately all contaminated clothing. Rinse skin with plenty of water for at least 15 minutes until slippery feeling disappears. Seek medical attention immediately. Wash clothing before reuse.
In case of eye contact: Rinse cautiously with water for several minutes lifting lower and upper eyelids occasionally. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention immediately.
In case of ingestion: Do not induce vomiting.Rinse the mouth and lips with water if the person is conscious, then transfer to hospital urgently.

4.2. Most important symptoms and effects, both acute and delayed

Sympthoms: Sodium hydroxide is severely corrosive to the eyes, mucous membranes and exposed areas of skin.
Risks:
- By ingestion: severe burns to the digestive tract, risk of perforation of the alimentary canal, state of shock.
- By skin contact: very corrosive for the skin, severe burns, severe lesions, scarring (sometimes retractile), and dermatitis possible in the case of repeated contact.
- By eye contact: corrosive for the eyes, severe lesions possibly with lasting effects if the eyes are not rinsed immediately, harm to all the eye tissues, risk of sight loss.
- By inhalation: corrosive for respiratory tract.Causes severe skin burns and eye damage.

4.3 Indication of immediate medical attention and special treatment needed
Perform endoscopy in all cases of suspected sodium hydroxide ingestion. In cases of severe esophageal corrosion, the use of therapeutic doses of steroids should be considered. General supportive measures with continual monitoring of gas exchange, acid-base balance, electrolytes and fluid intake are also required. If skin burns are present, treat as any thermal burn after decontamination.

5. FIRE - FIGHTING MEASURES

5.1 Extinguishing media
Suitable extinguishing media: All media. For large fire use powder, foam extinguishing agents or carbon dioxide. Avoid water use if possible. *Adding water to caustic solution generates large amounts of heat and steam!*

Unsuitable extinguishing media: none known

5.2 Special hazards arising from the substance or mixture
Specific hazards during fire fighting / Specific hazards arising from the chemical
Not considered to be a fire hazard. Sodium hydroxide can react with certain metals, such as aluminum and zinc to generate flammable hydrogen gas. Contact with moisture or water may generate sufficient heat to ignite nearby combustible materials.

5.3 Advice for firefighters
Special protective equipment for fire-fighters: Firefighters should wear proper protective equipment and self contained breathing apparatus with full face-piece operated in positive pressure mode. Avoid generation of dust. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

6. ACCIDENTAL RELEASE MEASURES

6.1 . Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep dust levels to a minimum.
Keep unprotected persons away.

Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8).
Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).
Avoid humidification.

For emergency responders
Keep dust levels to a minimum.
Ensure adequate ventilation.
Keep unprotected persons away.
Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8).
Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).
Avoid humidification.

6.2. Environmental precautions

Spillages or uncontrolled discharges into watercourses must be IMMEDIATELY alerted to the Environmental Agency or other appropriate regulatory body. Collect spillage in containers, seal securely and deliver for disposal according to local regulations.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up / Methods for containment:
Contain and recover when possible. Avoid generating dusty conditions. Do not flush caustic residues to sewer. Residues from spills can be diluted with water, neutralized with diluted acid such as acetic and hydrochloric. Absorb neutralized caustic residues on clay, sand, vermiculite or other absorbent material and place in a chemical waste container for disposal.
Refer to section 13 for disposal of spilled material.

6.4 Reference to other sections
Additional advice: Refer to section 8, 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Protective measures: Special attention is required when caustic soda is handled. All workers should be properly trained in the required safe handling and first aid procedure. Persons handling

caustic soda must always wear protective clothing, close-fitting chemical worker`s safety goggles, hard hat and rubber gloves, in order to avoid any contact with hand, skin or eyes. Do not wear contact lenses when handling this product. It is also advisable to have individual pocket eyewash. Keep dust levels to a minimum. Minimize dust generation

Advice on general occupational hygiene: Avoid inhalation or ingestion and contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no drinking, eating and smoking at the workplace. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home.

7.2. Conditions for safe storage, including any incompatibilities
The substance should be stored under dry conditions. Any contact with air and moisture should be avoided. Sodium hydroxide wrapped in original packaging will be store in a cool, dry, well-ventilated area away from incompatible substances. Protect containers from damage.
Incompatibles: do not store in aluminum, zinc, tin and lead containers. Do not store or mix with water, acids, flammable liquids, organic halogens compounds, nitro methane.
Never add water to a corrosive. Always add corrosives to water. When mixing with water, stir small amounts in slowly. Use cold water to prevent excessive heat generation.

7.3 Specific end use(s)
Please check the identified uses from Section 1.2.
For more information please see the relevant exposure scenario, available via your supplier/given in the Annex I.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit (OEL), 8 h TWA: 2 mg/m³ respirable dust of sodium hydroxide with a few exceptions (Czech Republic - 1.0 mg/m³; Poland – 0.5 mg/m³)
Short-term exposure limit (STEL), 15 min: 2 mg/m³ respirable dust of sodium hydroxide

DNEL/PENEC values
DNEL long term inhalation, general population= 1,0 mg/m³
DNEL long term inhalation, workers= 1,0 mg/m³
PNEC aqua: not applicable
PNEC soil/groundwater: not applicable.

No PNEC was able to be calculated as the buffering capacity, the pH and its fluctuation are very specific to the ecosystem in question.

8.2. Exposure control

Engineering control: A system of local and / or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emission of the contaminant at its source, preventing dispersion of it into the general work area.

Personal protective equipment

Respiratory protection: If the exposure limit is exceeded, a half-face dust /mist respirator may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full face-piece dust /mist respirator may be worn for up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. For emergencies or instances where exposure levels are not known, use a full face-piece positive pressure, air supplied respirator. *Air -purifying respirators do not protect workers in oxygen deficient atmospheres!*
Hand protection: Wear rubber gloves. Guidelines for sodium hydroxide, greater than 70% RECOMMENDED (resistance to breakthrough longer than 8 hours): Neoprene rubber, Polyvinyl chloride. Recommendations are NOT valid for very thin Natural rubber, Neoprene, Nitrile and PVC gloves (0.3 mm or less).
Eye / Face protection: Chemical splash goggles and/or face shield must be worn when possibility exists for eye contact due to splashing or spraying liquid, airborne particles or vapor. Contact lenses must not be worn. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure area.
Skin protection: Wear impervious protective clothing including boots, lab coat, apron or coveralls as appropriate, to prevent skin contact.
Monitoring Methods: Monitoring the substance concentration (dust) in workplace may be required to confirm compliance with an OEL and adequacy of exposure control.
Environmental Exposure Control:
All ventilation systems should be filtered before discharge to atmosphere.
Avoid releasing to the environment.
Contain the spillage. Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body.

For detailed explanations of the risk management measures that adequately control exposure of the environment to the substance please check the relevant exposure scenario, available via your supplier.

Other precautions: Maintain shower, eye wash fountain and quick-drench facilities in work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance	white and hygroscopic flakes, prills or block
Odor	odorless

Important health, safety and environmental information

pH	alkaline
Boiling point	1390°C
Flash point	NA
Flammability	non flammable
Explosive properties	non explosive
Oxidizing properties	no oxidizing properties
Vapor pressure, 20 °C	NA
Specific density (water=1)	2.13 g/cm^3
Solubility in water	completely soluble in water
in ethanol, glycerol	soluble
Partition coefficient (log K_{ow})	NA
Viscosity, 20°C	NA

Other information

Melting point	318°C
Autoignition temperature	NA

10. STABILITY AND REACTIVITY

10.1. Reactivity

A violent reaction occurs with mineral or organic acids and ketones.
Sodium hydroxide is highly corrosive to certain metals and alloys: zinc, aluminium, tin, copper, lead, bronze, brass. Sodium hydroxide also destroys leather, strips paint and attacks certain

plastics, rubbers and coatings. Contact with nitro methane and other similar nitro compounds cause formation of shock-sensitive salts.

10.2 Chemical stability
Under normal conditions of use and storage (dry conditions), sodium hydroxide is stable.
Hygroscopic product sensitive to the carbon dioxide in the air (carbonation).

10.3 Possibility of hazardous reactions
Sodium hydroxide is a stable product; however certain risks exist in the presence of :
explosives such as nitrous compounds - reaction producing enough heat to detonate the explosive
vinyl chloride monomer- formation of chloroacetylene
tetrahydrofuran-explosion upon contact
sodium tetrahydroborate -gives off hydrogen with an explosion
pentachlorophenol- explosion and formation of toxic vapours
tetrachlorobenzene-explosion due to an increase in pressure
maleic anhydride - explosive decomposition

10.4 Conditions to avoid
Substances to be avoided: water, acid, zinc, aluminium, copper, alkali metals, alkaline earth metals, acetaldehyde, acroleine, acrylonitrile, allyl alcohol, halon, maleic anhydride, bromine, nitroparaffins, nitroaromatics, oleums, tetrahydrofuran.
Minimise exposure to air and moisture to avoid degradation. Avoid contact with incompatibles.

10.5 Incompatible materials
Certain metals and alloys: zinc, aluminium, tin, copper, lead, bronze, brass. Sodium hydroxide also destroys leather, strips paint and attacks certain plastics, rubbers and coatings. Water contact may generate large amounts of heat.

10.6 Hazardous decomposition products
Dangerous products of decomposition: by corrosion of metals, formation of flammable and explosive hydrogen

11. TOXICOLOGICAL INFORMATION

	Conclusions
Absorbtion	no bioaccumulation potential based on study results.
Acute toxicity	Sodium hydroxide is a corrosive substance and for this reason there is no need for further acute toxicity testing (EU RAR, 2007;

	section 4.1.2.2.3, page 65).
Irritation/Corrosion	Based on experimental results and according to the CLP Regulation No 1272/2008 Annex VI Table 3.1, sodium hydroxide is a skin corrosive category 1A at a concentration ≥ 5% (H314: Causes severe skin burns and eye damage) the concentration range for eye/skin irritation is 0,5 % ≤ C < 2 %
Sensitisation	Existing data do not demonstrate that NaOH is a skin sensitizer.
Repeated dose toxicity	No reliable studies were available. However, systemic effects of NaOH after repeated exposure are not expected to occur under normal handling and use and therefore NaOH has no specific organ repeated dose toxicity.
Mutagenity	Both the in vitro and the in vivo genetic toxicity tests indicated no evidence of mutagenic activity.
Carcinogenity	NaOH is of no concern with regard to carcinogenicity.
Toxicity for reproduction	NaOH is not toxic for reproduction.

12. ECOLOGICAL INFORMATION

In formation on environmental effects

The available data indicate that NaOH concentrations of 20 to 40 mg/l may be acutely toxic to fish and invertebrates (single species tests). Data on pH increases due to the addition of these amounts of NaOH in the used test waters are lacking. In waters with a relatively low buffering capacity, NaOH concentrations of 20-40 mg/l may result in a pH increase with one to several pH units (EU RAR, 2007; section 3.2.1.1.3, page 30).The OECD (2002) assigned a low code of reliability ('invalid' or 'not assignable') to all available tests, as in general the tests were not conducted according to the current test guidelines (EU RAR, 2007; section 3.2.1.1.4, page 30). Furthermore, in many tests reports there were no data on pH, buffer capacity and/or test medium composition, although this is essential information for toxicity tests with NaOH. This is the most important reason why most of the tests were considered 'invalid'. Despite this lack of valid data, there is no need for additional aquatic toxicity testing with NaOH, as all available tests resulted in a rather small range of toxicity values (acute toxicity tests: 20 to 450 mg/l; chronic toxicity test: ≥ 25 mg/l) and there are sufficient data on the pH ranges that are tolerated by major taxonomic groups.Moreover, a generic PNEC cannot be derived from single-species toxicity data for NaOH, as the pH of natural waters as well as the buffer capacity of natural waters show considerable differences and aquatic organisms/ecosystems are adapted to these specific natural conditions,

resulting in different pH optima and pH ranges that are tolerated (EU RAR, 2007; section 3.2.1.1.4, page 30). According to the OECD (2002), a lot of information is available about the relationship between pH and ecosystem structure and also natural variations in pH of aquatic ecosystems have been quantified and reported extensively in ecological publications and handbooks.

Aquatic Toxicity

Short-term toxicity to fish

The OECD (2002) assigned a low code of reliability ('invalid' or 'not assignable') to all available tests, as in general the tests were not conducted according to the current test guidelines (EU RAR, 2007; section 3.2.1.1.4, page 30). In many tests reports there were no data on pH, buffer capacity and/or test medium composition, although this is essential information for toxicity tests with NaOH. Despite of this, there is no need for additional aquatic toxicity testing with NaOH, as all available tests resulted in a rather small range of toxicity values (acute toxicity tests to fish: 35 to 189 mg/l) and there are sufficient data on the pH ranges that are tolerated by major taxonomic groups.

Long-term toxicity to fish

No valid long-term toxicity studies to fish are available. Despite of this, there is no need for further toxicity testing with NaOH, as all available tests resulted in a rather small range of toxicity values (chronic toxicity test: ≥ 25 mg/l) and there are sufficient data on pH ranges that are tolerated by major taxonomic groups (EU RAR, 2007; section 3.2.1.1.4, page 30).

Short-term toxicity to aquatic invertebrates

Ceriodaphnia sp. acute 48-h immobilization test according to the NSW Environment Protection Authority
EC50 (48h, fresh water) = 40 mg/L

Long-term toxicity to aquatic invertebrates: study scientifically unjustified
Justification: In water (including soil or sediment pore water), NaOH is present as the sodium ion (Na^+) and hydroxyl ion (OH^-), as solid NaOH rapidly dissolves and subsequently dissociates in water (EU RAR, 2007; section 3.1.3, page 24). Therefore, the only posssible effect would result from the pH effect. However, pH will remain within environmentally expected ranges.

Algae and aquatic plants: study scientifically unjustified

Toxicity to soil macro-organisms: The terrestrial compartment was not included in the targeted risk assessment (EU RAR, 2007, section 3.1.3.3, page 26), because it is not considered relevant for NaOH since if emitted to the soil, sorption to soil particles will be negligible.

Toxicity to terrestrial plants: There is no direct exposure of soil to NaOH based on the available uses.

Toxicity to birds: No exposure to birds is foreseen.
PNEC not applicable According to the EU RAR (2007; section 3.1.3.5, page 26) bioaccumulation in organisms is not relevant for NaOH. Based on this, there is no need to perform risk assessment for secondary poisoning.

12.2. Persistence and degradability: NaOH will rapidly dissolve and dissociate in water. Therefore, NaOH does not fulfil the P criterion (EU RAR, 2007; section 3.3.1.2, page 34).

12.3. Bioaccumulative potential: Bioaccumulation is not relevant for NaOH, therefore, NaOH does not meet the B criterion of the PBT criteria (EU RAR, 2007; section 3.3.1.2, page 34).

12.4. Mobility in soil
High water solubility indicates that sodium hydroxide will be found predominately in aquatic environment. During movement through soil some ion exchange will occur. Also, some of the hydroxide may remain in the aqueous phase and will move downward through soil in the direction of groundwater flow. Sodium hydroxide does not cause biological oxygen deficit.

12.5. Results of PBT and vPvB assessment
NaOH, does not fulfil the criteria for persistency, bioaccumulation and toxicity. Therefore, NaOH is not considered a PBT or vPvB substance (EU RAR, 2007; section 3.3.1.2, page 34).

13. DISPOSAL CONSIDERATIONS

Waste treatment: Whatever cannot be saved for recovery or recycling should be handled as hazardous waste and sent to an approved waste facility. Any disposal practice must be in compliance with all local and national law and regulations. Do not dump into any sewers, on the ground, or into any body of water.

Packaging treatment: The empty packaging must be destroying according with all local, regional and national regulations.

14. TRANSPORT INFORMATION

Solid Sodium hydroxide can be shipped according to transport regulations for dangerous goods, hazard class 8, Corrosive substance.

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Transport Labeling

Label no.8
Corrosive

RID/ADR

UN No.	1823
Proper shipping name	Solid Sodium Hydroxide
Hazard class	8
UN Packing Group	II
Classification code	C6

Danger panel 80/1824 (Hazard Identification No. 80) (UN Identification No 1824)

IMDG/IMO

UN No.	1823
Hazard class	8
UN Packing Group	II
Proper shipping name	Solid Sodium Hydroxide
EmS No.	F-A, S-B
Marine pollutant	No

IATA/IT-ICAO

Proper shipping name	Solid Sodium Hydroxide
UN No.	1823
Hazard class	8
UN Packing Group	II
IATA Label	Corrosive
Packaging Note Passenger	814
Packaging Note Cargo	816
Max. Quantity Passenger	15 kg
Max. Quantity Cargo	60 kg

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15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Authorisations:	Not required
Restrictions on use:	None
Other EU regulations:	Sodium Hydroxide is not a SEVESO substance, not ozone depleting substance and not a persistent organic pollutant.
WGK (Germany):	WGK 1 slightly water endangering

15.2 Chemical safety Assesment
A chemical safety assessment has been carried out for this substance.

16. OTHER INFORMATION

Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationsh.

16.1. Full text of H-Statements referred to under sections 2 and 3

H314 Causes severe skin burns and eye damage.
H290 May be corrosive to metals.
H315 Causes skin irritation
H319 Causes serious eye irritation

16.2 Full text of R-phrases referred to under sections 2 and 3
R35 Cause severe burns.

16.3. Full text of P-Statements referred to under sections 2 and 3.

P260:	Do not breathe dust/fume/gas/mist/vapours/spray.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P303 + P361 + P353:	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER or doctor/physician.

16.4. Full text of S-Statements referred to under sections 2 and 3.

(S1/2 - keep locked up and out of reach of children)
S26 - in case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S37/39 - wear suitable gloves and eye/face protection
S45 - in case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

16.5. Explanations for possible abbreviations mentioned in section 2
PBT: Persistent, bioaccumulative and toxic.
vPvB: Very persistent and very bioaccumulative.
ES: Exposure Scenario
WGK: Wassergefährdungsklasse (Water hazard class)
DNEL: Derived No Effect Level
PNEC: Predicted No-Effect Concentration

16.6. Revision

Revision 0

Disclaimer:
Oltchim provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. Furthermore, this safety data sheet is made up based on the legal requirements as set by EC 1907/2006 (REACH) and 453/2010. Further information received following the time scale as foreseen by REACH and the guidance policies as described in the REACH Implementation Programs will be added when it becomes available.

Annex I to SDS – Exposure Scenario

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Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2010 and Regulation 453/ 2010

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ANNEX I– EXPOSURE SCENARIO

Exposure Scenario 1: Manufacturing of liquid NaOH
List of all use descriptors
Sector of use (SU): SU 3, 8 Manufacture of bulk, large-scale substances
Product category (PC): not applicable
Process category (PROC): PROC1 Use in closed process, no likelihood of exposure PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC8a/b Transfer of chemicals from/to vessels/large containers at (non)dedicated facilities PROC9 Transfer of chemicals into small containers (dedicated filling line)
Article category (AC): not applicable
Environmental Release Category (ERC): ERC1 Manufacture of substances
EU Risk Assessment An EU risk assessment has been performed based on the Existing Substances Regulation (Council Regulation 793/93). A comprehensive risk assessment report has been finalised in 2007 and is available via internet: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/sodiumhydroxidereport416.pdf
Contributing exposure scenario controlling environmental exposure
Product characteristics
Liquid NaOH, all concentrations
Frequency and duration of use
Continuous
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Risk management measures related to the environment aim to avoid discharging NaOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH

changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised. In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms.

Conditions and measures related to external treatment or recovery of waste for disposal

Liquid NaOH waste should be reused or discharged to the industrial wastewater and further neutralized if needed.

Contributing exposure scenario controlling worker exposure

Product characteristic

Liquid NaOH, all concentrations

Frequency and duration of use/exposure

8 hours/day, 200 days/year

Technical conditions and measures at process level (source) to prevent release

Replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes:

- Use closed systems or covering of open containers (e.g. screens)
- Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.)
- Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)"

Technical conditions and measures to control dispersion from source towards the worker

Local exhaust ventilation and/or general ventilation is good practice

Organisational measures to prevent /limit releases, dispersion and exposure

- Workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safer procedures instructed by the employer.
- The employer has also to ascertain that the required PPE is available and used according to instructions

Conditions and measures related to personal protection, hygiene and health evaluation

- Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)
- Hand protection: impervious chemical resistant protective gloves
  - material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min

- material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min

- Eye protection: chemical resistant goggles must be worn. If splashes are likely to occur, wear tightly fitting safety goggles, face –shield
- Wear suitable protective clothing, aprons, shield and suits, if splashes are likely to occur, wear: rubber or plastic boots, rubber or plastic boots

Exposure estimation and reference to its source

Worker exposure:

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure can be neglected. Therefore, dermal exposure to NaOH was not quantified.

NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of NaOH after dermal or inhalation exposure are not expected to occur.

Based on NaOH measurements and following the proposed risk management measures controlling worker exposure, the reasonable worst-case inhalation exposure of 0.33 mg/m^3 (typical value is 0.14 mg/m^3) is below the DNEL of 1 mg/m^3.

Environmental exposure:

The aquatic effect and risk assessment only deals with the effect on organisms/ecosystems due to possible pH changes related to OH^- discharges, as the toxicity of the Na^+ ion is expected to be insignificant compared to the (potential) pH effect. The high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. When the risk management measures related to the environment are implemented, there is no exposure to the activated sludge of a sewage treatment plant and there is not exposure of the receiving surface water.

The sediment compartment is not considered, because it is not considered relevant for NaOH. If emitted to the aquatic compartment, sorption to sediment particles will be negligible.

Significant emissions to air are not expected due to the very low vapour pressure of NaOH). If emitted to air as an aerosol in water, NaOH will be rapidly neutralised as a result of its reaction with CO_2 (or other acids).

Significant emissions to the terrestrial environment are not expected either. The sludge application route is not relevant for the emission to agricultural soil, as no sorption of NaOH to particulate matter will occur in STPs/WWTPs. If emitted to soil, sorption to soil particles will be negligible. Depending on the buffer capacity of the soil, OH^- will be neutralised in the soil pore water or the pH may increase.

Bioaccumulation will not occur.

Exposure Scenario 2: Manufacturing of solid NaOH

List of all use descriptors

Sector of use (SU): SU 3, 8 Manufacture of bulk, large-scale substances

Product category (PC): not applicable

Process category (PROC): PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC8a/b Transfer of chemicals from/to vessels/large containers at (non)dedicated facilities
PROC9 Transfer of chemicals into small containers (dedicated filling line)

Article category (AC): not applicable

Environmental Release Category (ERC): ERC1 Manufacture of substances

EU Risk Assessment

An EU risk assessment has been performed based on the Existing Substances Regulation (Council Regulation 793/93). A comprehensive risk assessment report has been finalised in 2007 and is available via internet:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/sodiumhydroxidereport416.pdf

Contributing exposure scenario controlling environmental exposure
Product characteristics
Solid NaOH
Frequency and duration of use
Continuous
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Risk management measures related to the environment aim to avoid discharging NaOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised. In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms.
Conditions and measures related to external treatment or recovery of waste for disposal
There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to the industrial

SAFETY DATA SHEET

Препаред ин аццорданце wих Аннеџ Иофхе РЕАЦХ регулатион ЕЦ 19007/2006,
Регулатион (ЕЦ) 1272/2010 анд Регулатион 453/ 2010

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Sector of use (SU): SU 3, 8 Manufacture of bulk, large-scale substances

Product category (PC): not applicable

Process category (PROC): PROC1 Use in closed process, no likelihood of exposure

PROC2 Use in closed, continuous process with occasional controlled exposure

PROC3 Use in closed batch process (synthesis or formulation)

PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises

PROC8a/b Transfer of chemicals from/to vessels/large containers at (non)dedicated facilities

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Article category (AC): not applicable

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Contributing exposure scenario controlling environmental exposure
Product characteristics
Solid NaOH
Frequency and duration of use
Continuous
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Risk management measures related to the environment aim to avoid discharging NaOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised. In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms.
Conditions and measures related to external treatment or recovery of waste for disposal
There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to the industrial

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This information only concerns the above mentioned product and does not need to be valid if used with other product(s) or in any process. The information is to our best present knowledge correct and complete and is given in good faith but without warranty. It remains the user's own responsibility to make sure that the information is appropriate and complete for his special use of this product.

wastewater and further neutralized if needed.

Contributing exposure scenario controlling worker exposure

Product characteristic

Solid NaOH, all concentrations

Frequency and duration of use/exposure

8 hours/day, 200 days/year

Technical conditions and measures at process level (source) to prevent release

Replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes:

- Use closed systems or covering of open containers (e.g. screens)
- Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.)
- Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)"

Technical conditions and measures to control dispersion from source towards the worker

Local exhaust ventilation and/or general ventilation is good practice

Organisational measures to prevent /limit release, dispersion and exposure

- Workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safar procedures instructed by the employer.
- The employer has also to ascertain that the required PPE is available and used according to instructions

Conditions and measures related to personal protection, hygiene and health evaluation

- Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)
- Hand protection: impervious chemical resistant protective gloves
  - material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min
  - material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min
- Eye protection: chemical resistant goggles must be worn. If splashes are likely to occur, wear tightly fitting safety goggles, face –shield
- Wear suitable protective clothing, aprons, shield and suits, if splashes are likely to occur, wear: rubber

or plastic boots, rubber or plastic boots

Exposure estimation and reference to its source

Worker exposure:

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure can be neglected. Therefore, dermal exposure to NaOH was not quantified.

NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of NaOH after dermal or inhalation exposure are not expected to occur.

Based on NaOH measurements and following the proposed risk management measures controlling worker exposure, the reasonable worst-case inhalation exposure of 0.26 mg/m^3 (measured at the drumming/bagging place) is below the DNEL of 1 mg/m^3.

Environmental exposure:

The aquatic effect and risk assessment only deals with the effect on organisms/ecosystems due to possible pH changes related to OH^- discharges, as the toxicity of the Na^+ ion is expected to be insignificant compared to the (potential) pH effect. The high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. When the risk management measures related to the environment are implemented, there is no exposure to the activated sludge of a sewage treatment plant and there is not exposure of the receiving surface water.

The sediment compartment is not considered, because it is not considered relevant for NaOH. If emitted to the aquatic compartment, sorption to sediment particles will be negligible.

Significant emissions to air are not expected due to the very low vapour pressure of NaOH). If emitted to air as an aerosol in water, NaOH will be rapidly neutralised as a result of its reaction with CO_2 (or other acids).

Significant emissions to the terrestrial environment are not expected either. The sludge application route is not relevant for the emission to agricultural soil, as no sorption of NaOH to particulate matter will occur in STPs/WWTPs. If emitted to soil, sorption to soil particles will be negligible. Depending on the buffer capacity of the soil, OH^- will be neutralised in the soil pore water or the pH may increase.

Bioaccumulation will not occur.

Exposure Scenario 3: Industrial and Professional Use of NaOH

List of all use descriptors

Sector of use (SU): SU 1-24

Because sodium hydroxide has so many uses and is used so widely it can potentially be used in all sectors of end use (SU) described by the use descriptor system (SU 1-24). NaOH is used for different purposes in a variety of industrial sectors.

Product category (PC): PC 0-40

Sodium hydroxide can be used in many different chemical product categories (PC). It can be used for example as an adsorbent (PC2), metal surface treatment product (PC14), non-metal-surface treatment product (PC15), intermediate (PC19), pH regulator (PC20), laboratory chemical (PC21), cleaning product (PC35), water softener (PC36), water treatment chemical (PC37) or extraction agent. However, it could potentially also be used in other chemical product categories (PC 0 – 40).

Process category (PROC): PROC1 Use in closed process, no likelihood of exposure

PROC2 Use in closed, continuous process with occasional controlled exposure

PROC3 Use in closed batch process (synthesis or formulation)

PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises

PROC5 Mixing or blending in batch processes (multistage and/or significant contact)

PROC8a/b Transfer of chemicals from/to vessels/large containers at (non)dedicated facilities

PROC9 Transfer of chemicals into small containers (dedicated filling line)

PROC10 Roller application or brushing

PROC11Non industrial spraying

PROC13 Treatment of articles by dipping and pouring

PROC15 Use of laboratory reagents in small scale laboratories

The process categories mentioned above are assumed to be the most important ones but other process categories could also be possible (PROC 1 – 27).

Article category (AC): not applicable

Although sodium hydroxide can be used during the manufacturing process of articles, the substance is not expected to be present in the article. The article categories (AC) do not seem applicable for sodium hydroxide.

Environmental Release Category (ERC):
- ERC1 Manufacture of substances
- ERC2 Formulation of preparations
- ERC4 Industrial use of processing aids in processes and products, not becoming part of articles
- ERC6A Industrial use resulting in manufacture of another substance (use of intermediates)
- ERC6B Industrial use of reactive processing aids
- ERC7 Industrial use of substances in closed systems
- ERC8A Wide dispersive indoor use of processing aids in open systems
- ERC8B Wide dispersive indoor use of reactive substances in open systems
- ERC8D Wide dispersive outdoor use of processing aids in open systems
- ERC9A Wide dispersive indoor use of substances in closed systems

The environmental release categories mentioned above are assumed to be the most important ones but other industrial environmental release categories could also be possible (ERC 1 – 12).

Further explanations

Typical uses include: production of organic and inorganic chemicals, formulation of chemicals, production and whitening of paper pulp, production of aluminium and other metals, food industry, water treatment, production of textiles, professional end use of formulated products and other industrial uses.

EU Risk Assessment

An EU risk assessment has been performed based on the Existing Substances Regulation (Council Regulation 793/93). A comprehensive risk assessment report has been finalised in 2007 and is available via internet:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/sodiumhydroxidereport416.pdf

Contributing exposure scenario controlling environmental exposure

Product characteristics

Solid or liquid NaOH, all concentrations (0-100%), if solid: low dustiness class

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SAFETY DATA SHEET
Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2010 and Regulation 453/ 2010

SOLID SODIUM HYDROXIDE (FLAKES /PRILLS/BLOCK)

Revision:0 Last up date: Date issued: November 15, 2010 pag. 26/30

Frequency and duration of use
Continuous
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Risk management measures related to the environment aim to avoid discharging NaOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised. In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms.
Conditions and measures related to external treatment or recovery of waste for disposal
There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to the industrial wastewater and further neutralized if needed.
Contributing exposure scenario controlling worker exposure
Product characteristic
Solid or liquid NaOH, all concentrations (0-100%), if solid: low dustiness class
Frequency and duration of use/exposure
8 hours/day, 200 days/year
Technical conditions and measures at process level (source) to prevent release
For worker, both solid and liquid NaOH containing products at concentration > 2%: Replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes: • Use closed systems or covering of open containers (e.g. screens) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) • Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)"
Technical conditions and measures to control dispersion from source towards the worker
For worker, both solid and liquid NaOH containing products at concentration > 2%: Local exhaust ventilation and/or general ventilation is good practice
Organisational measures to prevent /limit releases, dispersion and exposure
For worker, both solid and liquid NaOH containing products at concentration > 2%:

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- Workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safer procedures instructed by the employer.
- The employer has also to ascertain that the required PPE is available and used according to instructions
- Where possible for professional use, use of specific dispensers and pumps specifically designed to prevent splashes/spills/exposure to occur.

Conditions and measures related to personal protection, hygiene and health evaluation

For worker and professional, both solid and liquid NaOH containing products at concentration > 2%:

- Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)
- Hand protection: impervious chemical resistant protective gloves
  - material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min
  - material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min
- If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face –shield
- If splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots, rubber or plastic boots

Exposure estimation and reference to its source

Exposure Scenario 4: Consumer Use of NaOH

List of all use descriptors

Sector of use (SU): SU 21 Private households

Product category (PC): PC 0-40

Sodium hydroxide can be used in many different chemical product categories (PC): PC 20, 35, 39 (neutralisation agents, cleaning products, cosmetics, personal care products). The other PCs are not explicitly considered in this exposure scenario. However, NaOH can also be used in other PCs in low concentrations e.g. PC3 (up to 0.01%), PC8 (up to 0.1%), PC28 and PC31 (up to 0.002%) but it can be used also in the remaining product categories (PC 0-40).

Process category (PROC): not applicable

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Article category (AC): not applicable

Environmental Release Category (ERC):
ERC8A Wide dispersive indoor use of processing aids in open systems
ERC8B Wide dispersive indoor use of reactive substances in open systems
ERC8D Wide dispersive outdoor use of processing aids in open systems
ERC9A Wide dispersive indoor use of substances in closed systems

The environmental release categories mentioned above are assumed to be the most important ones but other wide dispersive environmental release categories could also be possible (ERC 8 – 11b).

Further explanations

NaOH (up to 100%) is also used by consumers. It is used at home for drain and pipe cleaning, wood treatment and it also used to make soap at home. NaOH is also used in batteries and in oven-cleaner pads.

EU Risk Assessment

An EU risk assessment has been performed based on the Existing Substances Regulation (Council Regulation 793/93). A comprehensive risk assessment report has been finalised in 2007 and is available via internet:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/sodiumhydroxidereport416.pdf

Contributing exposure scenario controlling environmental exposure

Product characteristics

Solid or liquid NaOH, all concentrations (0-100%), if solid: low dustiness class

Conditions and measures related to external treatment or recovery of waste for disposal

This material and its container must be disposed of in a safe way (e.g. by returning to a public recycling facility). If container is empty, trash as regular municipal waste.

Batteries should be recycled as much as possible (e.g. by returning to a public recycling facility). Recovery of NaOH from alkaline batteries includes emptying the electrolyte, collection and neutralization with sulphuric acid and carbon dioxide.

Contributing exposure scenario controlling worker exposure

Product characteristic

Solid or liquid NaOH, all concentrations (0-100%), if solid: low dustiness class

Typical concentrations: floor strippers (<10%), hair straighteners (<2%), oven cleaners (<5%), drain openers (liquid: 30%, solid: <100%), cleaning products (<1.1%)

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Conditions and measures related to the design of the product

- It is required to use resistant labelling-package to avoid its auto-damage and loss of the label integrity, under normal use and storage of the product. The lack of quality of the package provokes the physical loss of information on hazards and use instructions.
- It is required that household chemicals, containing sodium hydroxide for more than 2%, which may be accessible to children should be provided with a child-resistant fastening (currently applied) and a tactile warning of danger (Adaptation to Technical Progress of the Directive 1999/45/EC, annex IV, Part A and Article 15(2) of Directive 67/548 in the case of, respectively, dangerous preparations and substances intended for domestic use). This would prevent accidents by children and other sensitive groups of society.
- It is advisable to deliver only in very viscous preparations
- It is advisable to delivery only in small amounts
- For use in batteries, it is required to use completely sealed articles with a long service life maintenance.

Conditions and measures related to information and behavioural advice to consumers

It is required that improved use instructions, and product information should always be provided to the consumers. This clearly can efficiently reduce the risk of misuse. For reducing the number of accidents in which (young) children or elderly people are involved, it should be advisable to use these products in the absence of children or other potential sensitive groups. To prevent improper use of sodium hydroxide, instructions for use should contain a warning against dangerous mixtures.

Instructions addressed to consumers:

- Keep out of reach of children.
- Do not apply product into ventilator openings or slots.

Conditions and measures related to personal protection and hygiene

For consumer, both solid and liquid NaOH containing products at concentration > 2%:

- Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)
- Hand protection: impervious chemical resistant protective gloves
- If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face-shield

Exposure estimation and reference to its source

Consumer exposure:

Acute/short term exposure was assessed only for the most critical use: use of NaOH in a spray oven cleaner. Consexpo and SprayExpo were used to estimate exposure. The calculated short-term exposure of 0.3 – 1.6 mg/m^3 is slightly higher than the long term DNEL for inhalation of 1 mg/m^3 but smaller than the short term occupational exposure limit of 2 mg/m^3. Furthermore, NaOH will be rapidly neutralised as a result of its reaction with CO_2 (or other acids).

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Environmental exposure:

Consumer uses relates to already diluted products which will further be neutralized quickly in the sewer, well before reaching a WWTP or surface water.

АЛКАЛОИД СКОПЈЕ

Safety Data Sheet – Безбедносен лист со податоци

Според **Регулативата (EC) No. 1907/2006**

Изработен на: 14.02.2011 год.
Верзија: 1

1. ПОДАТОЦИ ЗА ПРОИЗВОДОТ И ЗА КОМПАНИЈАТА

Име на производот: **СУЛФУРНА КИСЕЛИНА 95-97%**
Производител: Алкалоид АД, А. Македонски 12, Скопје, Р.Македонија
Телефон: 02 3104 000
Телефон во случај на опасност: 02 3104 392

2. ПОДАТОЦИ ЗА ОПАСНОСТ

2.1. Класификација на супстанцијата или на смесата

Класификација - Регулатива (EC) No 1272/2008
Оштетувања на кожата , Категорија 1A, H314
Корозивно за метали, Категорија 1, H290

2.2. Етикетирање

Сигнален збор
Опасност

Изјави за опасност

H314 Предизвикува тешки изгореници и оштетување на очите.
H290 Може да биде корозивно за метали.

2.3. Други опасности
Не се познати.

3. СОСТАВ / ПОДАТОЦИ ЗА КОМПОНЕНТИТЕ

Хемиска формула	H_2SO_4
CAS No	7664-93-9
EC No	231-639-5
Молекулска маса	98,08 g/mol

4. МЕРКИ ЗА ПРВА ПОМОШ

4.1. Опис на мерките за помош, во итни ситуации

Во случај на вдишување: свеж воздух. Повикајте лекар.

При контакт со кожата: измијте со многу вода. Ставете полиетилен-гликол 400. Веднаш отстранете ја контаминираната облека. Повикајте лекар.

При контакт со очите: исплакнете со многу вода. Повикајте офталмолог.

Во случај на проголтување: веднаш дајте вода (најмногу 2 чаши). Избегнете повраќање. Повикајте лекар. Не обидувајте се да неутрализирате.

4.2. Најважни симптоми и ефекти, акутни и одложени

Иритација и корозија.
Опасност од слепило!

4.3. Ознаки за итна медицинска помош/потреба од посебен третман

Нема достапни податоци .

5. ПОДАТОЦИ ЗА ПОЖАР И ЗА ЕКСПЛОЗИЈА

5.1. Средства за гаснење пожар
Соодветни средства за гаснење
Употреба на средства за гасење, согласно локалните околности и околината.

Несоодветни средства за гаснење
Нема ограничувања.

5.2. Специјални опасности предизвикани од супстанцијата или од смесата.
Производот не е запалив.
Околниот пожар може да ослободи штетни испарувања.
При пожарот можат да се создадат сулфурни оксиди.

5.3. Совети за пожарникари
Специјална заштитна облека за пожарникари
Останете во опасната зона само со апарат за дишење. Избегнете контакт со кожата со држење соодветно растојание или со носење соодветна заштитна облека.

Дополнителни информации
Изладете ги затворените, изложени на оган, контејнери со ладна вода. Оневозможете водата за гаснење пожар да дојде во контакт и да ја контаминира површинската вода или подземните води. Разбијте ги испарувањата со млаз од вода.

6. МЕРКИ ПРИ СЛУЧАЈНО ИСТЕКУВАЊЕ

6.1. Мерки за лична заштита, заштитна облека и процедури во случај на итност

Совет - избегнете контакт со супстанцијата. Не ги вдишувајте испарувањата. Евакуирајте ја опасната зона, видете ги процедурите за случај на итност, консултирајте експерт.

Совет за лица одговорни во случај на итност - заштитна опрема (види точка 8)

6.2. Мерки за заштита на околината
Не смее да се истура во одводните канали.

6.3. Методи и материјали за чистење
Видете можни ограничувања во однос на материјалите.
Внимателно соберете. Отстранете на соодветен начин за хемиски отпад.
Исчистете ја контаминираната зона.

6.4. Референци на други делови
Постапки за обработка на отпад (види точка 13)

7. РАКУВАЊЕ И СКЛАДИРАЊЕ

7.1. Предупредување за безбедно ракување
Прочитајте ги предупредувањата на етикетата.

7.2. Услови за безбедно складирање, вклучувајќи каква било инкомпатибилност .

Услови за простории за чување и контејнери
Да се чува добро затворено.
Температура на складирање – без ограничувања.

7.3. Посебна крајна употреба
Освен употребата опишана во точка 1.2, друга употреба не е предвидена .

8. КОНТРОЛА НА ИЗЛОЖЕНОСТ/ЛИЧНА ЗАШТИТА

8.1. Контролни параметри

8.2. Контрола на изложеност

Технички мерки
Приоритет им се дава на техничките мерки и соодветното изведување на работните операции, во однос на употребата на заштитна опрема. (види точка 7.1.)

Индивидуални мерки на заштита
Заштитната облека мора да се избере соодветно за секое работно место, во зависност од концентрацијата и од количината на опасните супстанции со кои се ракува. Отпорноста на заштитната облека кон хемикалии, треба да биде специфицирана од добавувачот.

Хигиенски мерки
Веднаш да се смени контаминираната облека. Употребете заштитен крем за кожа. Измијте ги лицето и рацете по работата со супстанцијата.

Заштита за очи/лице
Заштитни очила со округли стакла.

Заштита за раце
полн контакт

материјал од кој се изработени ракавиците	Viton (R)
дебелина на ракавиците	0,70 mm
време на продирање	> 480 min.

контакт при прскање

материјал од кој се изработени ракавиците	бутилна гума
дебелина на ракавиците	0,70 mm
време на продирање	> 120 min.

Останата заштитна опрема
Заштитна облека, отпорна на киселини.

Заштита на органите за дишење
Потребна во случај на создавање испарувања.
Препорачан тип на филтер - филтер P2 (согласно DIN 3181) за цврсти и за течни честички од отровни супстанции.

Контрола на изложеност на околината
Не истурајте ја во одводните канали.

9. ФИЗИЧКИ И ХЕМИСКИ СВОЈСТВА

9.1	Изглед	безбоен воден раствор
9.2	Мирис	без мирис
9.3.	pH (49g/l, 20°C)	0,3
9.4.	Точка на топење	-20°C
9.5.	Релативна густина (20°C)	1,84 g/cm^3
9.6.	Растворливост во вода (20°C)	растворливо (предупредување!ослободување на топлина)

10. СТАБИЛНОСТ И РЕАКТИВНОСТ

10.1. Реактивност
Корозивно.

10.2. Хемиска стабилност
Овој производ хемиски е стабилен при стандардни услови на чување.
(пр. собна температура)

10.3. Можни опасни реакции
Ризик од експлозија и/или создавање на отровни гасови, во конатк со:

Силни реакции со:
Вода, алкални метали, алкални компоненти, амонијак, алдехиди, ацетонитрил, земноалкални метали, киселини, метали, металоиди, оксиди на фосфорна киселина, хидриди, халоген-халоген компоненти, оксихалогени компоненти, перманганати, нитарти, карбиди, запаливи супстанции, органски растворувачи, нитрили, органски нитро компоненти, пероксиди, нитриди, феро компоненти, бромати, хлорати, амини, перхлорати, хидроген пероксид.

10.4. Услови кои треба да се избегнуваат
Силно загревање.

10.5. Несоодветни материјали
Животински/растителни ткива, метали.
Во контакт со метали се ослободува водороден гас.

10.6. Опасни производи на распаѓање
Во случај на пожар, види точка 5.

11. ТОКСИКОЛОШКИ ПОДАТОЦИ

11.1. Информации за токсиколошки ефекти

Акутна токсичност при вдишување
LC50
зајак
Доза: 510 mg/m^3, 2h (чиста супстанција)

Надразнување на кожата
зајак
Предизвикува изгореници.

Надразнување на очите
зајак
Опасност од тешки повреди на очите.
Опасност од слепило!

Генотоксичност in vitro
Резултат: негативен.

Тератогеност
Нема појава на тератогени ефекти, при експерименти со животни.

Специфична токсичност за одредени органи / составна токсичност-еднократна изложеност
Супстанцијата или смесата не е класифицирана како отров за одредени органи.

Специфична токсичност за одредени органи / составна токсичност-повторена изложеност
Супстанцијата или смесата не е класифицирана како отров за одредени органи.

Опасност од вдишување
Супстанцијата не е класифицирана како отровна при вдишување.

11.2. Дополнителни информации
При вдишување на испарувања: оштетување на слузницата. При контакт со кожа: сериозни изгореници. При контакт со очите: изгореници. При голтање: сериозна болка, повраќање, дијареа.
Дополнителни информации:
Да се ракува во склад со важечката индустриска хигиенска и безбедносна пракса .

12. ЕКОЛОШКИ ПОДАТОЦИ

12.1. Токсичност
Отровно за риби
LC50
Доза: 16-29 mg/l, 96h

Отровно за daphnia и за останатите водени без`рбетници
EC50
Доза: 29 mg/l, 24h

12.2. Постојаност и разградливост
Нема достапни информации.

12.3. Биоакумулациски потенцијал
Нема достапни информации.

12.4. Движење во почвата
Нема достапни информации.

12.5. Други штетни дејства
Дополнителни еколошки податоци
Биолошко дејство:
Формира корозивни смеси со водата, дури и разредена.
Штетно дејство поради промена на pH.
Ја загадува водата за пиење, доколку навлезе во почвата и водите.

Останати еколошки податоци
Не дозволувајте да дојде во контакт со водите, отпадните води или со почвата.

13. НАЧИН НА ОТСТРАНУВАЊЕ

Отпадот треба да се отстрани во согласност со националната, регионалната и со локалната регулатива за контрола на животната средина.

14. ИНФОРМАЦИИ ЗА ТРАНСПОРТ

ADR / RID	UN 1830	SULFURIC ACID, 8, II
IATA	UN 1830	SULFURIC ACID, 8, II
IMDG	UN 1830	SULFURIC ACID, 8, II

15. РЕГУЛАТОРНИ ИНФОРМАЦИИ

15.1. Закони/прописи кои се однесуваат на безбедноста, здравјето и на околината, а кои се специфични за супстанцата или мешавината

15.2. Проценка за безбедност на хемикалијата
За овој производ не се врши проценка на хемиска безбедност .

Изјави за опасност

H290 Може да биде корозивно за метали.
H302 Штетно ако се проголта.
H314 Предизвикува тешки изгореници и оштетувања на очите.

Изјави за предупредување

P280 Да се носат заштитни ракавици/заштитна облека/заштита за очи/ заштита за лице.
P301+P330+P331 ДОКОЛКУ СЕ ПРОГОЛТА: исплакнете ја устата. НЕ предизвикувајте повраќање.
P309 ДОКОЛКУ сте изложени или не се чувствувате добро
P310 Веднаш повикајте ја Клиниката за токсикологија или побарајте лекарска помош.
P305+P351+P338 ВО КОНТАКТ СО ОЧИ: внимателно исплакнете со вода, неколку минути. Извадете ги контактните леќи, ако ги има и ако можат безбедно да се извадат. Продолжете со плакнење.

16. ОСТАНАТИ ИНФОРМАЦИИ

Производот е сигурен доколку се употребува според пропишаните услови и во согласност со примената наведена на амбалажата и/или во техничките упатства. За која било друга употреба на производот, во комбинација со друг производ или процес, одговорноста ја презема корисникот.

Други посебни мерки: нема податоци

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POTASSIUM HYDROXIDE TR FLAK.MIN90% B25KG

Version 1.0
Revision Date 31.03.2005

Print Date 09.09.2008

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product information

Trade name	:	POTASSIUM HYDROXIDE TR FLAK.MIN90% B25KG
Use	:	chemical intermediate
Supplier	:	Brenntag CEE GmbH Linke Wienzeile 152 AT 1060 Wien
Responsible Department	:	Abteilung Produktsicherheit
Telephone	:	+43 (1) 599 9 50
Telefax	:	+43 (1) 597 0 200
Emergency telephone number	:	Vergiftungsinformationszentrale: +43 (1) 406 43 43

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature

chemical intermediate
potassium hydroxide
Concentration: <= 100,00 %
CAS-No.: 1310-58-3 EC-No.: 215-181-3 Index-No.: 019-002-00-8
Symbol(s) C R-phrase(s): R22, R35

For the full text of the R phrases mentioned in this Section, see Section 16.

3. HAZARDS IDENTIFICATION

Risk advice to man and the environment

Symbol(s) : C Corrosive

R22 Harmful if swallowed.
R35 Causes severe burns.

4. FIRST AID MEASURES

General advice	:	Take off contaminated clothing and shoes immediately.
Inhalation	:	Remove to fresh air. Consult a physician.
Skin contact	:	Wash off immediately with plenty of water for at least 15 minutes. Take off contaminated clothing and shoes immediately. Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
Eye contact	:	Rinse thoroughly with plenty of water, also under the eyelids. Call a physician immediately.
Ingestion	:	Clean mouth with water and drink afterwards plenty of water.

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Do not induce vomiting. Call a physician immediately.

6. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. The product itself does not burn.
Specific hazards during fire fighting	:	Gives off hydrogen by reaction with metals. Sweep up to prevent slipping hazard.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Wear appropriate body protection (full protective suit)
Additional advice	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	:	Use personal protective equipment. Contaminated surfaces will be extremely slippery.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system. If the product contaminates rivers and lakes or drains inform respective authorities.
Methods for cleaning up	:	Use mechanical handling equipment. Dispose of in accordance with local regulations. Flush with plenty of water.

7. HANDLING AND STORAGE

Handling

Advice on safe handling	:	Keep container tightly closed. Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Advice on protection against fire and explosion	:	The product is not flammable. Gives off hydrogen by reaction with metals. Risk of explosion.

Storage

Requirements for storage areas and containers	:	Keep in an area equipped with alkali resistant flooring. Suitable materials for containers: polyethylene containers; Unsuitable materials for containers: aluminium; zinc
Further information on storage conditions	:	Keep container tightly closed and dry. Product is hygroscopic.
German storage class	:	8: Corrosive Substances

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Components with workplace control parameters

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Not applicable.

Personal protective equipment

Respiratory protection	:	Respirator must be worn if exposed to dust.
Hand protection	:	Wear suitable gloves. The glove material has to be impermeable and resistant to the product / the substance / the preparation. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The following materials are suitable: natural rubber; polychloroprene; nitrile rubber; polyvinylchloride; fluorocarbon rubber
Eye protection	:	tightly fitting safety goggles
Body Protection	:	impervious clothing
Hygiene measures	:	Take off all contaminated clothing immediately. Do not breathe dust or spray mist. Avoid contact with the skin and the eyes. Keep away from food, drink and animal feedingstuffs. Smoking, eating and drinking should be prohibited in the application area. Wash hands before breaks and at the end of workday.

Engineering measures

Refer to protective measures listed in sections 7 and 8.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	:	solid
Colour	:	white
Odour	:	odourless

Safety data

Melting point/range	:	approx. 410 °C
Boiling point/range	:	1.320 °C
Flash point	:	not applicable
Explosive properties	:	Product is not explosive.
Density	:	approx. 2,1 g/cm3; 20 °C
Water solubility	:	approx. 1.150 g/l; 20 °C
pH	:	14; 100 g/l; 20 °C

10. STABILITY AND REACTIVITY

Materials to avoid	:	water; amines; ammonia; light metals; strong acids; ammonium compounds; halogenated compounds; organic materials
Hazardous reactions	:	Exothermic reaction with strong acids. Reacts violently with

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water.

General advice : strongly hygroscopic

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity : LD50 rat 273 mg/kg
Skin irritation : rabbit corrosive effects
Eye irritation : rabbit Risk of serious damage to eyes. severely corrosive; blindness

Sensitization : Did not cause sensitization on laboratory animals.

Further information : If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. After eye contact: Risk of blindness! Handle in accordance with good industrial hygiene and safety practice.

12. ECOLOGICAL INFORMATION

Elimination information (persistence and degradability)

Biodegradability : The methods for determining biodegradability are not applicable to inorganic substances.

Ecotoxicity effects

Toxicity to fish : LC50 Gambusia affinis 80 mg/l 96 h
Toxicity to daphnia : LC50 Daphnia 10 - 100 mg/l 96 h
Toxicity to algae : LC50 10 - 100 mg/l 96 h
Toxicity to bacteria : LC50 10 - 100 mg/l 96 h

Further information on ecology

Additional ecological information : Do not flush into surface water or sanitary sewer system. Neutralization is normally necessary before waste water is discharged into water treatment plants. Should not be released into the environment.

13. DISPOSAL CONSIDERATIONS

Product : Do not let product enter drains. Dispose of as special waste in compliance with local and national regulations. Waste codes should be assigned by the user based on the application for which the product was used.

packaging : Empty remaining contents. Dispose of as unused product. Dispose of in accordance with local regulations.

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14. TRANSPORT INFORMATION

ADR	:	UN-No	1813
		Class	8
		Packaging group	II
		Classification Code	C6
		ADR/RID-Labels	8
		Risk No.	80
		Description of the goods	POTASSIUM HYDROXIDE, SOLID
RID	:	UN-No	1813
		Class	8
		Packaging group	II
		Classification Code	C6
		ADR/RID-Labels	8
		Risk No.	80
		Description of the goods	POTASSIUM HYDROXIDE, SOLID
IMDG	:	UN-No	1813
		Class	8
		Packaging group	II
		ADR/RID-Labels	8
		EmS	F-A
		Description of the goods	POTASSIUM HYDROXIDE, SOLID

16. REGULATORY INFORMATION

Labelling according to EC Directives
The product is classified and labelled in accordance with EC directives or respective national laws.

Symbol(s)	C	Corrosive
R-phrase(s)	R22	Harmful if swallowed.
	R35	Causes severe burns.
S-phrase(s)	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Hazardous components which must be listed on the label:
- potassium hydroxide

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National legislation

Water contaminating class (Germany) : WGK 1 slightly water endangering

Waste Code : 52404
Regulation : (** Phrase language not available: [E] CUST - ZZ43-0000000007 *)

16. OTHER INFORMATION

Text of R-phrases referred to under headings 2 and 3:

R22 Harmful if swallowed.
R35 Causes severe burns.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. Restricted to professional users. Attention - Avoid exposure - obtain special instructions before use.

This safety datasheet only contains information relating to safety and does not replace any product information or product specification.

# Indicates updated section.

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АЛКАЛОИД СКОПЈЕ

Safety Data Sheet – Безбедносен лист со податоци

Според **Регулативата (EC) No. 1907/2006**

Изработен на: 15.02.2011 год.
Верзија: 1

1. ПОДАТОЦИ ЗА ПРОИЗВОДОТ И ЗА КОМПАНИЈАТА

Име на производот: **ХЛОРОВОДОРОДНА КИСЕЛИНА 30%**
Производител: Алкалоид АД, А. Македонски 12, Скопје, Р.Македонија
Телефон: 02 3104 000
Телефон во случај на опасност: 02 3104 392

2. ПОДАТОЦИ ЗА ОПАСНОСТ

2.1. Класификација на супстанцијата или на смесата

Класификација - Регулатива (EC) No 1272/2008
Специфичен отров за одредени органи, при еднократна изложеност,
Категорија 3, H335
Оштетувања на кожата , Категорија 1A, H314
Корозивно за метали, Категорија 1, H290

2.2. Етикетирање

Сигнален збор
Опасност.

Изјави за опасност

H335 Може да предизвика иритација на респираторните органи.
H314 Предизвикува тешки изгореници и оштетување на очите.
H290 Може да биде корозивно за метали.

2.3. Други опасности
Не се познати.

3. СОСТАВ / ПОДАТОЦИ ЗА КОМПОНЕНТИТЕ

Воден раствор.

Хемиска формула	HCl
CAS No	7647-01-0
EC No	231-595-7
Молекулска маса	36,461 g/mol

4. МЕРКИ ЗА ПРВА ПОМОШ

4.1. Опис на мерките за помош, во итни ситуации

Во случај на вдишување: свеж воздух. Повикајте лекар.

При контакт со кожата: измијте со многу вода. Ставете полиетилен-гликол 400. Веднаш отстранете ја контаминираната облека. Повикајте лекар.

При контакт со очите: исплакнете со многу вода. Повикајте офталмолог.

Во случај на проголтување: веднаш дајте вода (најмногу 2 чаши). Избегнете повраќање. Повикајте лекар. Не обидувајте се да неутрализирате.

4.2. Најважни симптоми и ефекти, акутни и одложени

Иритација и корозија, кашлање, недостаток на воздух.
Опасност од слепило!

4.3. Ознаки за итна медицинска помош/потреба од посебен третман

Нема достапни податоци .

5. ПОДАТОЦИ ЗА ПОЖАР И ЗА ЕКСПЛОЗИЈА

5.1. Средства за гаснење пожар
Соодветни средства за гаснење
Употреба на средства за гасење, согласно локалните околности и околината.

Несоодветни средства за гаснење
Нема ограничувања.

5.2. Специјални опасности предизвикани од супстанцијата или од смесата.
Производот не е запалив.
Околниот пожар може да ослободи штетни испарувања.
При пожарот можат да се создаде хлороводороден гас.

5.3. Совети за пожарникари
Специјална заштитна облека за пожарникари
Останете во опасната зона само со апарат за дишење. Избегнете контакт со кожата со држење соодветно растојание или со носење соодветна заштитна облека.

Дополнителни информации
Оневозможете водата за гаснење пожар да дојде во контакт и да ја контаминира површинската вода или подземните води. Разбијте ги испарувањата со млаз од вода.

6. МЕРКИ ПРИ СЛУЧАЈНО ИСТЕКУВАЊЕ

6.1. Мерки за лична заштита, заштитна облека и процедури во случај на итност

Совет - избегнете контакт со супстанцијата. Не ги вдишувајте испарувањата. Обезбедете соодветна вентилација. Евакуирајте ја опасната зона, видете ги процедурите за случај на итност, консултирајте експерт.

Совет за лица одговорни во случај на итност - заштитна опрема.
(види точка 8)

6.2. Мерки за заштита на околината

Не смее да се истура во одводните канали.

6.3. Методи и материјали за чистење
Покријте ги одводните канали. Соберете и испумпајте. Видете можни ограничувања во однос на материјалите.
Внимателно соберете со неутрален материјал, кој апсорбира течности.
Отстранете на соодветен начин за хемиски отпад.
Исчистете ја контаминираната зона.

6.4. Референци на други делови
Постапки за обработка на отпад (види точка 13)

9. РАКУВАЊЕ И СКЛАДИРАЊЕ

7.1. Предупредување за безбедно ракување
Прочитајте ги предупредувањата на етикетата.

7.2. Услови за безбедно складирање, вклучувајќи каква било инкомпатибилност .

Барања за простор за складирање и контејнери.
Забрането складирање во метални контејнери.
Да се чува добро затворено.
Температура на складирање – без ограничувања.

7.3. Посебна крајна употреба
Освен употребата опишана во точка 1.2, друга употреба не е предвидена .

10. КОНТРОЛА НА ИЗЛОЖЕНОСТ/ЛИЧНА ЗАШТИТА

8.1. Контролни параметри

8.2. Контрола на изложеност

Технички мерки
Приоритет им се дава на техничките мерки и соодветното изведување на работните операции, во однос на употребата на заштитна опрема.
(види точка 7.1.)

Индивидуални мерки на заштита
Заштитната облека мора да се избере соодветно за секое работно место, во зависност од концентрацијата и од количината на опасните супстанции со кои се ракува. Отпорноста на заштитната облека кон хемикалии, треба да биде специфицирана од добавувачот.

Хигиенски мерки
Веднаш да се смени контаминираната облека. Употребете заштитен крем за кожа. Измијте ги лицето и рацете по работата со супстанцијата.

Заштита за очи/лице
Заштитни очила со округли стакла.

Заштита за раце
полн контакт

материјал од кој се изработени ракавиците	нитрилна гума
дебелина на ракавиците	0,11mm
време на продирање	> 480 min.

контакт при прскање

материјал од кој се	природен латекс

изработени ракавиците
дебелина на ракавиците 0,60 mm
време на продирање > 120 min.

Останата заштитна опрема
Заштитна облека, отпорна на киселини.

Заштита на органите за дишење
Потребна во случај на создавање испарувања.
Препорачан тип на филтер - филтер E-(P2

Контрола на изложеност на околината
Не истурајте ја во одводните канали.

9. ФИЗИЧКИ И ХЕМИСКИ СВОЈСТВА

9.1	Изглед	безбоен воден раствор
9.2	Мирис	карактеристичен
9.3.	pH (49g/l, 20°C)	<1
9.4.	Точка на топење	-40°C
9.5.	Точка на вриење	84°C
9.6.	Релативна густина (20°C)	1,16 g/cm^3
9.7.	Растворливост во вода (20°C)	растворливо

10. СТАБИЛНОСТ И РЕАКТИВНОСТ

10.1. Реактивност
Опасни реакции не се очекуваат, доколку со производот се ракува согласно упатството.

10.2. Хемиска стабилност
Овој производ хемиски е стабилен при стандардни услови на чување.
(пр. собна температура)

10.3. Можни опасни реакции
Алкални метали, конц. сулфурна киселина

Егзотермна реакција со:

Амини, калиум перманганат, соли на оксихалогени киселини, семиметални оксиди, семиметални водородни компоненти, алдехиди, винилметил етер.

Ризик од самозапалување или формирање на запаливи гасови и испарувања со:

карбиди, литиум силицид, флуорин, алуминиум, хидриди, формалдехид, метали, силни алкални средства, сулфиди.

10.4. Услови кои треба да се избегнуваат
Нема достапни информации.

10.5. Несоодветни материјали
Метали.
Ослободува водород при реакција со метали.

10.6. Опасни производи на распаѓање
Во случај на пожар, види точка 5.

11. ТОКСИКОЛОШКИ ПОДАТОЦИ

11.1. Информации за токсиколошки ефекти

Акутна орална токсичност
Симптоми: при проголтување, сериозни изгореници во устата и грлото, како и опасност од перфорација на хранопроводникот и стомакот.

Акутна токсичност при вдишување
LC50
зајак
Доза: 3124 ppm, 1h (чиста супстанција)
Симптоми: изгореници на слузницата, кашлање, недостаток на воздух.

Надразнување на кожата
зајак
Предизвикува сериозни изгореници.

Надразнување на очите
зајак
Опасност од тешки повреди на очите.
Опасност од слепило!

Специфична токсичност за одредени органи / составна токсичност-еднократна изложеност
Може да предизвика иритација на респираторните органи.

Специфична токсичност за одредени органи / составна токсичност-повторена изложеност
Супстанцијата или смесата не е класифицирана како отров за одредени органи.

Опасност од вдишување
Супстанцијата не е класифицирана како отровна при вдишување.

11.2. Дополнителни информации

Системски ефекти:
После латентен период – колапс на системот за циркулација.
Дополнителни информации:
Да се ракува во склад со важечката индустриска хигиенска и безбедносна пракса .

15. ЕКОЛОШКИ ПОДАТОЦИ

12.1. Токсичност
Нема достапни информации.

12.2. Постојаност и разградливост
Нема достапни информации.

12.3. Биоакумулациски потенцијал
Нема достапни информации.

12.4. Движење во почвата
Нема достапни информации.

12.5. Други штетни дејства
Дополнителни еколошки податоци
Нема квантитативни информации за еколошките ефекти од овој производ.

Биолошко дејство:
Формира корозивни смеси со водата, дури и разредена.

Останати еколошки податоци

Не дозволувајте да дојде во контакт со водите, отпадните води или со почвата.

16. НАЧИН НА ОТСТРАНУВАЊЕ

Отпадот треба да се отстрани во согласност со националната, регионалната и со локалната регулатива за контрола на животната средина.

17. ИНФОРМАЦИИ ЗА ТРАНСПОРТ

ADR / RID UN 1789 HYDROCHLORIC ACID, 8, II

IATA UN 1789 HYDROCHLORIC ACID, 8, II

IMDG UN 1789 HYDROCHLORIC ACID, 8, II

15. РЕГУЛАТОРНИ ИНФОРМАЦИИ

15.1. Закони/прописи кои се однесуваат на безбедноста, здравјето и на околината, а кои се специфични за супстанцата или мешавината

15.2. Проценка за безбедност на хемикалијата
За овој производ не се врши проценка на хемиска безбедност .

Изјави за опасност

H290 Може да биде корозивно за метали.
H335 Може да предизвика иритација на респираторните органи.
H314 Предизвикува тешки изгореници и оштетувања на очите.

Изјави за предупредување

P260 Не ги вдишувајте испарувањата.
P280 Да се носат заштитни ракавици/заштитна облека/заштита за очи/ заштита за лице.
P301+P330+P331 ДОКОЛКУ СЕ ПРОГОЛТА: исплакнете ја устата. НЕ предизвикувајте повраќање.
P309+ P310 ДОКОЛКУ сте изложени или не се чувствувате добро: Веднаш повикајтеја Клиниката за токсикологија или побарајте лекарска помош.
P305+P351+P338 ВО КОНТАКТ СО ОЧИ: внимателно исплакнете со вода, неколку минути. Извадете ги контактните леќи, ако ги има и ако можат безбедно да се извадат. Продолжете со плакнење.

16. ОСТАНАТИ ИНФОРМАЦИИ

Производот е сигурен доколку се употребува според пропишаните услови и во согласност со примената наведена на амбалажата и/или во техничките упатства. За која било друга употреба на производот, во комбинација со друг производ или процес, одговорноста ја презема корисникот.

Други посебни мерки: нема податоци.

Безбедносен лист со податоци за

АЛКАЛОИД СКОПЈЕ

МОРФИН БАЗА

според Регулативата (на Европската Заедница) бр. 1907/2006

1. Идентификација на производот и производителот

Шифра	3000250; 3000878; 3000879
Име	Морфин база
Синоними	Морфин; Морфиа; Морфина, Морфинан-3,6-диол, 7,8-дидехидро-4,5-епокси-17-метил-(5алфа, 6алфа); 7,8-дидехидро-4,5-епокси-17-метилморфинан-3,6-диол; 7,8-дидехидро-4,5-алфа-епокси-17-метил-морфинан-6-алфа-диол
Употреба	фармацевтска суровина -аналгетик(наркотик)
Производител	Алкалоид АД бул. Александар Македонски бр.12 1000 Скопје, Македонија тел. 02 3104 000
Телефони за итни потреби	Брза помош 194 ; Клиника за токсикологија 3147-103 Пожарна 193 ; Полиција 192

2. Идентификација на опасности

GHS класификација	/
ЕС класификација	**T** Токсично **F** Запаливо R 11: Многу запаливо R 39/23/24/25: Токсично: опасност од многу тешки неповратни ефекти доколку се вдише, при допир со кожата и доколку се проголта
Преглед на опасности	Опасност! Може да биде фатален ако се проголта. Штетен е ако се инхалира или апсорбира преку кожата. Алерген. Изложеноста може да доведе до алергенска реакција. Наркотик.

3. Состав/ информација за состојките

Формула	$C_{17}H_{19}NO_3$
CAS-No.	57-27-2
EINECS-No.	200-320-2
Содржина	min 75%
Моларна маса	285,34 g/mol

4. Мерки за прва помош

Генерален совет	Покажете ја етикетата и безбедносниот лист на медицинскиот персонал.
По вдишување	Изнесете го лицето на свеж воздух. Ако не дише, дадете му вештачко дишење. Доколку дишењето е отежнато, дадете му кислород. Побарајте медицинска помош.
По голтање	Исплакнете ја усната шуплина и веднаш предизвикајте повраќање. Не давајте ништо преку уста, на лице во безсознание. Веднаш побарајте медицинска помош. Забелешка за лекарот: Испразнете го желудникот на жртвата. Обезбедете соодветна респираторна размена. Дадете интравенозни течности и/или вазопресори. Применете Налоксон(опијатен антагонист) интравенозно. Повторете го давањето на Налоксон инекциите, ако е потребно. Пратете ја состојбата на пациентот, бидејки делувањето на опијатот може да го надмине делувањето на антагонистот, па ќе биде потребен додатен Налоксон или инфузија со антагонистот.
По контакт со очите	Веднаш измијте ги со многу вода, најмалку 15 min, подигајќи ги очните капаци и побарајте медицинска помош.
По контакт со кожа	Отстранете ја контаминираната облека и измијте ја кожата со многу вода, најмалку 15 min. Побарајте медицинска помош. Измијте ја облеката пред повторна употреба.

5. Мерки при пожар

Средства за гасење	Вода, јаглероден диоксид, пена, сув хемиски прашок.
Специфични опасности	Како и повеќето органски соли, можен е пожар, при покачени температури или при контакт со извор на оган. Прашината дисперзирана во воздухот во доволни концентрации и во присуство на извор на оган, е потенцијална опасност од експлозија. Потребно е да се заземји технолошката опрема, за да се избегне создавање на статички електрицитет.
Заштитни мерки	Евакуирајте го персоналот кој не е обучен за сузбивање пожари. Лицата кои го гасат пожарот треба да се со потполна заштитна опрема и гас маска.

6. Мерки при несакано истекување/ослободување

Претпазливост на персоналот	Избегнувајте контакт со супстанцата. Обезбедете добра вентилација на просторот. Отстранете ги изворите на оган.
Методи за ограничување на излеаното и чистење	Во овие активности мора да учествуваат најмалку две лица, кои со соодветна лична заштитна опрема и со алат што не искри, внимателно, без да се создава прашина, ја собираат количината во контејнери за понатамошно отстранување. Количината на собраниот материјал треба да се измери и документира. Потоа со вода и детергент, исчистете ги контаминираните површини.
Еколошка претпазливост	Истурената количина да не се испушта во одводи.

7. Ракување и складирање

Безбедно ракување	Избегнувајте вдишување, контакт со кожата и очите. Измијте ги рацете и лицето по ракувањето.
Складирање	Чувајте ја супстанцата добро затворена, во контејнери што не пропуштаат светлина, во ладен, сув и добро вентилиран простор. КОНТРОЛИРАНА СУПСТАНЦА. Локацијата и видот на просторот за складирање, како и начинот на чување на супстанцата мораат да бидат во согласност со националната и меѓународната регулатива за опојни дроги(DEA).

8. Контроли на изложеност/лична заштита

Контролни параметри	Граници на концентрација во воздухот или биолошки гранични вредности на професионална изложеност, не се воспоставени.
Инжинерски контроли	Ракувајте во простор со адекватна генерална и/или локална вентилација. Се препорачува локална вентилација, за да се спречи емисијата на контаминентот во целиот работен простор.
Лична заштитна опрема	Заштита на очите/лицето: Хемиски заштитни очила или заштитна маска. Заштита на кожата: Носете соодветна заштитна облека и заштитни ракавици. Респираторна заштита: Носете маска за заштита од прашина, филтер тип P1(EN 143) или N95 (US), тестирани и одобрени од стандардите NIOSH(US) или CEN(EU).

9. Физички и хемиски карактеристики

Изглед	Бел до слабожолт кристален прашок
Мирис	Без мирис
Праг на миризливост	Не е пронајдена информација
pH	8.5 (заситен раствор)
Температура на топење/стврднување	Од 195 ^{o}C до 200^{o}C
Температура на вриење	254 ^{o}C (1,0134 hPa)
Температура на палење	Не е пронајдена информација
Стапка на испарување	Не е пронајдена информација
Запаливост	Не е пронајдена информација
Граници на запаливост/експлозивност	Не е пронајдена информација
Притисок на пареа	Не е пронајдена информација
Релат. густина на пареа	Не е пронајдена информација
Релативна густина	1,31

Растворливост	Многу слаба растворливост во вода., хлороформ и етер. Слаба растворливост во алкохол. Супстанцата е растворлива во оцетна киселина.
Партициски коефициент (n-октанол/вода)	Не е пронајдена информација
Температура на самозапалување	Не е пронајдена информација
Температура на разградување	Не е пронајдена информација
Вискозност	Не е пронајдена информација

10. Стабилност и реактивност

Реактивност	Не е пронајдена информација.
Стабилност	Стабилен е ако се чува на темно, затворен, во сув и ладен простор.
Можни опасни реакции	Не е пронајдена информација.
Услови кои треба да се избегнуваат	Изложување на светлина, бидејќи доведува до потемнување на материјалот, загревање, извори на оган, некомпатибилни материјали.
Некомпатибилни материјали	Алкалии, јаки оксиданси, танин, боракс, железо(III) хлорид, јодиди, олово(II) ацетат, жива(II) хлорид и соли на злато.
Опасни продукти од распаѓање	При горење може да ослободува јаглероден моноксид, јаглероден диоксид, азотни оксиди.

11. Информации за токсичност

Нумерички вредности за токсичност

Информации од досегашните испитувања за токсичноста на материјалот можат да се најдат под бројот: QC7875000 (CAS# 57-27-2) во RTECS#

-акутна токсичност

рута	организам	доза
орално	глушец	LD50 524 mg/kg
орално	стаорец	LD50 335 mg/kg

-канцерогеност

Нема канцерогено дејство. Не се наоѓа на листите на канцерогени материјали, на ESHA, ACGIH, IARC, NIOSH, NTP и OSHA.

-мутагеност

Ја зголемува DNA фрагментацијата на човечките лимфоцити инвитро.
Ја зголемува фрекфенцијата на микронуклеидите на клетките на коскената срж инвиво.
Предизвикува незрелост на црвените крвни зрнца кај глушец при тест инвиво.
Предизвикува хромозомски промени на лимфоцитите и сперматозоидите на глувците инвиво.

-репродуктивна токсичнот	Не предизвикува дефектност на новородените стаорци, при изложеност од 20mg/kg на мајката стаорец за време на бременоста. Ја зголемува стапката на смртност на новородените кај стаорецот при изложеност од 70mg/kg/дневно, од петиот до дваесетиот ден од бременоста. Кај подмладокот на глувци, стаорци и хрчаци, третирани со големи дози на морфин во текот на бременоста, се појавуваат трајни промени во оформувањето и функцијата на ЦНС, како и пораст на ретардација кај ембрионите.
Потенцијални ефекти врз здравјето	
При инхалација:	Ги иритира респираторните патишта и предизвикува кивавица или кашлање, но има и анестетски ефект. Инхалација на големи количини предизвикува едема на белите дробови, вртоглавица и респираторни потешкотии.
При голтање:	Токсичен е и наркотичен. Негативните ефекти се манифестираат со: вртоглавица, гадење, повраќање, констипација, стомачни болки, чешање на кожата, црвенило или отоци на лицето, нервоза, губење апетит, лажно чувство за добро расположение, сува уста, дремливост, низок крвен притисок, зачестено или зголемено уринирање со потешкотии, конфузија, нерамномерно срцебиење, зголемено потење, неконтролирани движења на мускулите, главоболка, необична слабост и чувство на умор, несвестица, визуелни нарушувања, кошмари, отежнато дишење. При предозираност, предизвикува ладење и лепливост на кожата, конфузија, конвулзии, силна вртоглавица, изразена дремливост, низок крвен притисок, тежок немир, фиксирани зеници, голема слабост, губење свест, споро дишење, срцебиење, депресија на ЦНС, респираторен или кардиоваскуларен колапс, кома и смрт. Дозата која може да предизвика смрт кај човекот е 120-250mg.
При контакт со кожа:	Освен што може да предизвика алергиска реакција, не предизвикува здравствени проблеми при контакт со кожата, но постои можност од апсорпција во телото преку кожата, во случај на воспаление или оштетеност на кожата.
При контакт со очи:	Незначително ги иритира очите, но има силен наркотичен ефект(стеснување на зениците). Исто така окото може да послужи како рута на апсорпција во телото.
Хронична изложеност:	Можни се појави на преосетливост или пак зависност.
Преосетливост (хиперсензитивност)	Кај некои поединци може да се појави преосетливост на супстанцата, која се манифестира со чешање и егзема на кожата, кашлица, затнат нос, астма и други алергични појави. Сензитивноста може да се развие веднаш по контактот или по повеќегодишна изложеност.

12. Еколошки информации

Екотоксичност	Не е пронајдена информација
Разградливост	Не е пронајдена информација
Биоакумулативен потенцијал	Не е пронајдена информација
Мобилност во почва	Не е пронајдена информација
Додатни еколошки информации	Не е пронајдена информација

13. Начин на отстранување

Методи за отстранување	Хемикалијата, како и нејзината празна амбалажа, треба да се отстрани на начин регулиран со националната, регионалната и локалната регулатива. Бидејќи се работи за контролирана супстанца, отстранувањето треба да биде во согласност со регулативата за опојни дроги (DEA).

14. Информации за транспорт

UN број	1544 (ADR/RID; IMDG; IATA)
UN транспортно име	Алкалоиди, цврсто
Транспотрна класа на опасност	6.1
Група на пакување	III
Еколошка опасност	Не е пронајдена информација
Специфични мерки на претпазливост	Не е пронајдена информација

15. Регулаторни информации

GHS-етикетирање

Пиктограм за опасност : /
Сигнален збор : /
Изјави за опасност : /
Изјави за претпазливост : /

EC-етикетирање

Симбол : 

F Запаливо 

T Токсично

R-фрази:
11 Многу запаливо
39/23/24/25 Токсично: опасност од многу тешки неповратни ефекти доколку се вдише, при допир со кожата и доколку се проголта

S-фрази:
7 Да се чува цврсто затворен
16 Да се чува подалеку од извори на оган
22 Не вдишувајте од прашината
24/25 Да се избегнува контакт со кожата и очите
36/37 Да се носи соодветна заштитна облека и ракавици
45 Во случај на незгода или ако не се чуствувате добро, веднаш побарајте медицински совет
51 Користете го само во добро вентилирани простории

Статус во регулативите за безбедност, здравје и околина

Морфин алкалоид CAS# 57-27-2						
TSCA	EC	Japan	Austral.	Korea	DSL	NDSL
осло-боден	да	не	да	не	не	не

NFPA рангирање Здравје: 3 Запаливост: 1 Реактивност: 1

Други регулативи Drug Enforcement Agency (DEA)
Controlled Products Regulations (CPR)

16. Други информации

Информации за ревизија:

Издаден од: ПЦ Фармација
Производство фармацевтски суровини

Дата на прво издание: 07.2010

Верзија/дата: 1/ 07.2010

Контакт: tradonic@alkaloid.com.mk

Дадените информации се базираат на сегашниот степен на нашето знаење и информациите за супстанцата кои тековно се на располагање. Овој документ е наменет како водич за соодветно постапување со материјалот, од страна на соодветно обучени лица. Го карактеризира производот, доколку се употребува според пропишаните услови. Овој документ не претставува гаранција за квалитетот на серијата производ. За било каква штета причинета од несоодветно постапување со производот, одговорноста ја превзема корисникот.

Кратенки и акроними:

GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EC: European Community
CAS: Chemical Abstracts Service
EINECS: European Inventory of Existing Chemical Substances
DEA: Drug Enforcement Agency
CPR: Controlled Products Regulations
RTECS: Registry of Toxic Effects of Chemical Substances
LD50: Lethal Dose 50 *(median concentration of a toxicant that will kill 50% of the test animals within a designated period)*
ESHA: Environmental, Safety and Health Affairs *(EU)*
ACGIH: American Conference of Governmental Industrial Hygienists
IARC: International Agency for Research on Cancer *(World Health Organization)*
NIOSH: National Institute for Occupational Safety and Health
CEN: European Committee for Standardization
NTP: National Toxicology Program
OSHA: Occupational Safety & Health Administration
UN numbers or UN IDs : are four-digit numbers that identify hazardous substances in the framework of international transport
ADR/RID: Agreement on Dangerous Goods by Road/ Regulations Concerning the International Transport of Dangerous Goods by Rail

IMDG: International Maritime Dangerous Goods
IATA: International Air Transport Association
TSCA: Toxic Substances Control act
NFPA: National Fire Protection Association

Мазут -масло за горење

(Превземено од ОКТА)

Безбедност

-Ризик од пожар доколку мазутот се загреал до температура повисока од точката на палење
-Иако мазутот не е класифициран како запалив, лесните јагленоводородни пареи може да се формираат на површината на резервоарот во концентрации во опсег на запаливост.

Животна средина

-При излевање во вода, мазутот формира слој од јагленоводороди на површината при што се намалува природната вентилација.
-При излевање на мала количина мазут на почва, значителен дел ќе испари, а остатокот ќе се абсорбира во погорните аеробни слоеви на почвата.
-При излевање на поголема количина мазут на почва, значителен дел ќе навлезе во аеробните горни слоеви на почвата, со веројатност за загадување на подземните води. Се смета за невозможно дека овие компоненти ќе траат доволно долго за да претставуваат опасност по здравјето на населението.

Против пожарни мерки

-Да се користи сув прав, пена, јаглерод диоксид.
-За справување со големи пожари потребно е реагирање од страна на соодветно обучен персонал и користење пена.

Ракување и складирање

-Утовар/истовар температура, ^{o}C: 60-70
-Температура на складирање, ^{o}C: 60-70

R Фраза:

R45 Може да предизвика рак
R51/53 Токсичен за водените организми, предизвикува штети во водена средина

S Фраза:

S53 Да се избегнува изложување на мазут
S45 Да се избегнува изложување на мазут
S61 Да се избегнува испуштање во животната средина

Прилог 2 на ПОГЛАВЈЕ IV

NATURAL SOURCING
Specialists in Connecticut Ingredients
341 Christian Street, Oxford, CT 06478 USA
Tel: (203) 267-6061 Fax: (203) 267-6065
www.naturalsourcing.com info@naturalsourcing.com

MATERIAL SAFETY DATA SHEET

MAGNESIUM STEARATE

MSDS

1. PRODUCT NAME AND COMPANY IDENTIFICATION	
Product Name:	MAGNESIUM STEARATE
Product Use:	Personal Care Formulations
Company Name:	Natural Sourcing
Company Address:	341 Christian Street, Oxford, CT 06478, USA
Date Issued:	09/12/2009
Emergency Telephone Number:	Chemtrec Tel: (800) 262-8200

2. COMPOSITION/INGREDIENT INFORMATION	
Chemical Formula:	$(C_{17}H_{35}COO)_2Mg$
Composition:	
Magnesium stearate	100%
Hazardous Components:	None
Exposure Limits:	N/A
CAS #:	557-04-0
EINECS #:	
Toxicology Data on Ingredients:	Not Applicable

3. HAZARDS IDENTIFICATION	
Routes of Entry:	* Ingestion
Potential Acute Health Effects:	Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.

4. FIRST AID MEASURES	
Eyes:	Flush with plenty of water or eye wash solution for 15 minutes. WARM water MUST be used. Get medical attention if irritation persists.
Skin:	Wash with soap and water. Cover irritated skin with an emollient. Get medical attention if irritation occurs.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as collars, ties, belts or waistbands.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
Medical Conditions Generally Aggravated by Exposure:	None

5. FIRE FIGHTING MEASURES	
Flammability of Product:	May be combustible at high temperatures.
Flash Point (Method Used):	Not Available
Flammable Limits:	LEL: Not Established UEL: Not Established
Auto Ignition Temperature:	Not Available
Hazardous Combustion Products:	CO, CO2
Conditions Under Which Flammability Could Occur:	Not Available
Extinguishing Media:	* Dry Chemical * Carbon Dioxide * Foam Note: Do not use water jet.
Special Firefighting Procedures:	* Combustible material. * Use air supplied equipment for fighting interior fires. * Cool fire exposed containers with water spray.
Unusual Fire & Explosion Hazards:	Not established

6. ACCIDENTAL RELEASE MEASURES (STEPS FOR SPILLS)	
Personal Protection:	N/A
Methods for Cleaning Up:	* Sweep up and dispose of in an appropriate waste disposal container according to local and regional authority requirements. * Wash area with soap and water. LARGE SPILL: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

7. HANDLING AND STORAGE	
Handling	
Safe Handling:	* Wear safety glasses. Avoid contact with eyes. * Keep away from oxidizing agents, excessive heat and sources of ignition. * Empty containers pose a fire risk. Evaporate the residue under a fume hood. * Ground all equipment containing material. * Do not breathe dust.
Storage	
Requirements for Storage Areas and Containers:	Store in a cool, dry location, in a sealed container in a well ventilated area.

8. EXPOSURE CONTROL/PERSONAL PROTECTION	
Engineering Controls:	Use process enclosures. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Ensure that eyewash stations an safety showers are proximal to the work area.
Personal Protection	
Eye:	Safety glasses should be worn.
Skin/Body:	Lab coats, gloves.
Respiratory:	Approved/certified dust respirator or equivalent.
Ventilation:	Handle in well ventilated areas.
Other:	Evaluate need based on application. Slip proof shoes may be worn where spills may occur.
Work/Hygiene Practice:	Normal work and hygiene practices for handling chemicals.
Exposure Limits:	TWA: 10 from ACGIH (TLV) [United States] Consult local authorities for acceptable exposure limits.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Physical State:	Solid
Color:	White
Odor:	Neutral
Specific Gravity (H2O = 1):	1.026
pH:	Not Available
Melting Point:	88 °C (190.4 °F)
Solubility in Water:	Slightly soluble in cold water.

10. STABILITY AND REACTIVITY	
Stability:	Stable
Conditions to Avoid:	Not Available
Incompatibility (Materials to Avoid):	Not Available
Hazardous Decomposition or Byproducts:	Not Available
Hazardous Polymerization:	Will Not Occur

11. TOXICOLOGICAL INFORMATION	
Routes of Entry:	Ingestion
Toxicity to Animals:	LD50: Not Available LC50: Not Available
Chronic Effects on Humans:	May cause damage to the following organs: Liver, Skin
Other Toxic Effects on Humans:	Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.
Irritancy:	Skin: Irritant Eyes: Irritant

Carcinogenicity:	Not Available
Reproductive Toxicity:	Not Available
Teratogenicity:	Not Available
Mutagenicity:	Not Available
Notes:	This substance may be toxic to liver, skin. Repeated or prolonged exposure to the substance can produce target organ damage.
Name of toxicologically synergistic products:	Not Available

12. ECOLOGICAL INFORMATION

Ecological Information:	Not Available
BOD5 and COD:	Not Available
Products of Biodegradation:	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Toxicity of the Products of Biodegradation:	The products of degradation are more toxic.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods:	Do not put into sewer lines. Dispose of according to local, state and federal regulations.

14. TRANSPORT INFORMATION

DOT Classification:	Not a DOT controlled material.
Class/Division:	Not restricted
Proper Shipping Name:	N/A
Label:	None
Packing Group:	N/A
ID Number:	N/A
Hazard:	N/A

15. REGULATORY INFORMATION

Federal & State Regulations:	California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Magnesium stearate California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: Magnesium stearate TSCA 8(b) inventory: Magnesium stearate
Other Regulations:	Not Available
WHMIS Canada:	Not controlled under WHMIS (Canada)
DSCL (EEC):	This product is not classified according to the EU regulations.

HMIS (USA):	Health Hazard: 1 Fire Hazard: 1 Reactivity: 0 Personal Protection: E
National Fire Protection Association (USA):	Health Hazard: 1 Flammability: 1 Reactivity: 0 Specific Hazard: Protective Equipment: Gloves Lab Coat Dust respirator. Be Sure to use an approved/certified respirator or equivalent. Safety Glasses

16. ADDITIONAL INFORMATION

This information is provided for documentation purposes only.

The complete range of conditions or methods of use are beyond our control therefore we do not assume any responsibility and expressly disclaim any liability for any use of this product. Information contained herein is believed to be true and accurate however, all statements or suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local laws and local regulations remains the responsibility of the user.

This safety sheet cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers.

ROQUETTE
Italia S.p.A

SAFETY DATA SHEET

REF : K50-112T
November 05 - P 1/4

PRODUCT : MAIZE STARCH B

acc 91/155/CEE and its amendments

01. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION:

01.1	Chemical product name	: MAIZE STARCH B
01.2	Supplier	: ROQUETTE FRERES
	Address	: 62136 LESTREM FRANCE
	Telephone/Telefax	: 03.21.63.36.00 / 03.21.63.38.50
	Emergency telephone	: ROQUETTE FRERES FRANCE
		: 03.21.63.36.00 / 03.21.63.38.50

02. COMPOSITION/INFORMATION ON INGREDIENTS:

02.1	Substance	: yes
02.2	Common chemical name	: native maize starch
02.3	CAS number	: 9005-25-8
02.4	N° EINECS	: 232-679-6
02.5	Ingredients contributing to the hazard	: not applicable

03. HAZARDS IDENTIFICATION:

03.1	Most important hazards	: potential for formation of explosive air / dust cloud
03.2	Specific hazards	: explosion hazards, see § 3.1
03.3	Other information	: not classified under CHIP regulation

04. FIRST-AID MEASURES:

04.1	Inhalation	: remove to fresh air ; if symptoms develop, seek medical advice
04.2	Eye contact	: rinse with plenty of water, seek medical attention
04.3	Skin contact	: wash with water and soap
04.4	Ingestion	: seek medical attention according to symptoms

05. FIRE-FIGHTING MEASURES:

05.1	Extinguishing media	: water spray
05.2	Non-suitable extinguishing media	: CO2 : inactive Powder : hazards of dust cloud formation

06. ACCIDENTAL RELEASE MEASURES:

06.1	Personal precautions	: follow recommendations for protection § 8
06.2	Environmental precautions	: generally no or weak hazard for water (biodegradable product)
06.3	Methods for cleaning up	: collect mechanically, vaccuum up, if necessary wash with water. to eliminate residues , see § 13

07. HANDLING AND STORAGE:

07.1	Handling Technical measures	: follow recommendations for personal protection § 8 Premises where dust can be generated must be

ROQUETTE ITALIA - Società per Azioni con Socio Unico - Roquette Frères SA (FRANCIA)
SEDE LEGALE, DIREZIONE E STABILIMENTO: 15063 CASSANO SPINOLA (AL) - VIA SERRAVALLE, 26
TELEFONO: 0143 774 1 r.a., TELEX: 210161 ROQUET 1, TELEFAX: 0143 477 295
CAPITALE SOCIALE INT. VERS. € 5.165.000 - CODICE FISCALE PARTITA IVA N. 00161980065 - REG. IMP. N 242/27/275
TRIBUNALE DI TORTONA - C.C.I.A.A ALESSANDRIA N. 73302

ROQUETTE
Italia S.p.A

SAFETY DATA SHEET

REF : K50-112T
November 05 - P 2/4

PRODUCT : MAIZE STARCH B

acc 91/155/CEE and its amendments

		identified per areas and equipped according to the ATEX directive. (*)
	Precautions	: avoid dust formation or dispersion in the air
	Safe handling advice	: follow general recommendations for handling of dusty products Any handling and/or storage of products must be suited to the explosibility characteristics of each product, which are well known by the customer. He is the sole responsible person and must therefore take action to avoid any accident hazard (explosion in particular) and/or product alteration. (*)
07.2	Storage	
	Technical measures	: Bulk storage silos must be compliance with the ATEX directive. (*)
	Storage conditions	: store in a cool and dry area
	Incompatible products	: strong oxidizing agents
	Packaging materials	: paper bag , flexible bulk container, bulk
08. EXPOSURE CONTROLS/PERSONAL PROTECTION:		
08.1	Control parameters	: follow the national regulation applicable to non specific total dusts AEL <= 10 mg/m3 (France)
08.2	Personal protective equipment	
	Respiratory protection	: dust mask in case of dust occurence
	Eye protection	: appropriate goggles (optional)
	Hand protection	: not necessary
	Skin and body protection	: none
08.3	Hygiene measures	: general hygiene practices for chemical products handling
09. PHYSICAL AND CHEMICAL PROPERTIES:		
09.1	Physical state	: powder
	Colour	: white to light yellowish
	Odour	: neutral
09.2	pH (concentration)	: 4.5 - 6.0 at 20 %
09.3	Boiling temperature	: not applicable
	Flashpoint	: not applicable
	Autoignition temperature	: 480 °C (GG - cloud)
09.4	Explosion properties	: min ignition energy : approx 225 mJ max explosion pressure : approx 8.5 bars KST : approx 124 bar m/s Class (VDI 3673 ST) : 1 min explosible concentration : 30 - 60 g/m3 (ref : INERIS, similar to maize starch)
09.5	Density	: approx 0.50 kg/l
09.6	Solubility	: insoluble at 20 °C

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ROQUETTE
Italia S.p.A

SAFETY DATA SHEET

REF : K50-112T
November 05 - P 3/4
acc 91/155/CEE and its amendments

PRODUCT : MAIZE STARCH B

		soluble at 90 °C (approx 150 g/l)
10. STABILITY AND REACTIVITY:		
10.1 Stability	:	stable with respect to storage conditions §7
10.2 Hazardous reactions	:	air / dust mixture (explosion hazards)
10.3 Materials to avoid	:	strong oxidizing agents
10.4 Hazardous decomposition products	:	typical decomposition products : Carbon monoxide and dioxide, oxygen, water
11. TOXICOLOGICAL INFORMATION:		
11.1 Acute toxicity	:	DL50 : not available
11.2 Local effects	:	rubbing may cause mechanical skin irritation for hypersensitive individuals
11.3 Other information	:	no known toxicity
12. ECOLOGICAL INFORMATION:		
12.1 Persistence/Degradability	:	biodegradable product
12.2 Bioaccumulation	:	not applicable, product metabolized by organisms
12.3 Ecotoxicity	:	CL50 : not available
13. DISPOSAL CONSIDERATIONS:		
13.1 Waste from residues	:	can be eliminated as a solid waste (common industrial waste) or incinerated in approved treatment plant conforming with applicable regulations and legislation
13.2 Contaminated packaging	:	single use packaging eliminate or recycle according to local regulations
14. TRANSPORT INFORMATION:		
14.1 International regulations	:	not applicable
14.2 UN number	:	none

	RID/ADR	RTMDR	IMDG	IATA/OACI
Class	n a	n a	n a	n a
Group, number or page				
Labelling				
Danger code				
Product code				

15. REGULATORY INFORMATION:		
15.1 Labelling according to EEC standards	:	not required
Hazard symbol	:	not applicable

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ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : K50-112T
November 05 - P 4/4
PRODUCT : MAIZE STARCH B acc 91/155/CEE and its amendments

15.2 Local regulations.....	:	product conforming with following regulations : * FDA - CFR 21 : §§ 176.170 & 176.180 * BgVV XXXVI : point B.I.3

16. OTHER INFORMATION:

Note :
This bulletin completes the Technical Directions for use but is not a substitute for them.
Attention is drawn to the risks encountered when the product is used in applications other than those for which intended.
It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.
All information and instructions provided in this Safety Data Sheet (SDS) is made with no warranty ; they are based on the current state of our knowledge at the latest revision date indicated.
* Updating :
The modified texts of the former versions are marked with an asterisk (*).

Quality Assurance Lestrem, 9 May 2011

ROQUETTE ITALIA - Società per Azioni con Socio Unico - Roquette Frères SA (FRANCIA)
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TELEFONO: 0143 774 1 r.a., TELEX: 210161 ROQUET 1, TELEFAX: 0143 477 295
CAPITALE SOCIALE INT. VERS. € 5.165.000 - CODICE FISCALE PARTITA IVA N. 00161980065 - REG. IMP. N 242/27/275
TRIBUNALE DI TORTONA - C.C.I.A.A ALESSANDRIA N. 73302

MON-ECO INDUSTRIES INC -- METHOCEL K15M HYDROXYPROPYL METHYLCELLULOSE -- 6810-00N033411

========== Product Identification ==========

Product ID:METHOCEL K15M HYDROXYPROPYL METHYLCELLULOSE
MSDS Date:08/11/1986
FSC:6810
NIIN:00N033411
MSDS Number: BPQHB
=== Responsible Party ===
Company Name:MON-ECO INDUSTRIES INC
Address:5 JOANNA COURT
City:EAST BRUNSWICK
State:NJ
ZIP:08916
Country:US
Info Phone Num:201-257-7942
Emergency Phone Num:800-424-9300(CHEMTREC)
CAGE:3Z312
=== Contractor Identification ===
Company Name:MON-ECO INDUSTRIES INC
Address:5 JOANNA COURT
Box:City:EAST BRUNSWICK
State:NJ
ZIP:08816-2108
Country:US
Phone:908-257-7942
CAGE:3Z312

========== Composition/Information on Ingredients ==========

Ingred Name:HYDROXYPROPYL METHYLCELLULOSE
CAS:9004-65-3
RTECS #:NF9125000
Fraction by Wt: >99%

Ingred Name:SUPP DATA: STRUCTURAL LAYERS.
RTECS #:9999999ZZ

Ingred Name:RESP PROT: DEMAND MODE, OR A NIOSH/MSHA APPROVED
SUPPLIED-AIR RESPIRATOR.
RTECS #:9999999ZZ

Ingred Name:WASTE DISP METH: WASTE DISPOSAL.
RTECS #:9999999ZZ

========== Hazards Identification ==========

LD50 LC50 Mixture:LD50:(ORAL,RAT)10 G/KG
Routes of Entry: Inhalation:YES Skin:NO Ingestion:YES
Reports of Carcinogenicity:NTP:NO IARC:NO OSHA:NO
Health Hazards Acute and Chronic:ACUTE: INHAL: BREATHING DUST MAY
IRRITATE NOSE/THROAT & CAUSE COUGHING AND CHEST DISCOMFORT. EYE:
DUSTS MAY IRRITATE. SKIN: MECHANICAL INJURY ONLY. INGEST: VERY LOW
ACUTE AND CHRONIC ORAL TOXICITY. CH RONIC: NO SPECIFIC INFORMATION
AVAILABLE.
Explanation of Carcinogenicity:NOT RELEVANT
Effects of Overexposure:SEE HEALTH HAZARDS.
Medical Cond Aggravated by Exposure:NONE REPORTED.

========== First Aid Measures ==========

First Aid:INHAL: REMOVE TO FRESH AIR. GIVE ARTIFICIAL RESPIRATION IF
NOT BREATHING. GET IMMEDIATE MEDICAL ATTENTION. EYE: IMMEDIATELY
FLUSH WITH LOTS OF RUNNING WATER FOR @ LEAST 15 MINUTES, LIFTING
LIDS OCCASI ONALLY. GET IMMEDIATE MEDICAL ATTENTION. SKIN: WASH OFF
IN FLOWING WATER. INGEST: NO EFFECT EXPECTED. CALL MD IMMED .

========== Fire Fighting Measures ==========

Extinguishing Media:WATER FOG.
Fire Fighting Procedures:WEAR NIOSH/MSHA APPROVED SCBA AND FULL
PROTECTIVE EQUIPMENT .
Unusual Fire/Explosion Hazard:UNDER CONFINED CNDTNS, A FINE DUST CLOUD
OF MATL IN AIR MAY CAUSE DUST EXPLOSION IF IGNITED AS WHEN EXPOS TO
HEAT/SPARKS/OPEN FLAME. MIN EXPLOS DUST (SUPP DATA)

========== Accidental Release Measures ==========

Spill Release Procedures:WEAR PROT EQUIP INCL RUB BOOTS/GLOVES/APRON &
A NIOSH/MSHA APPRVD FULL FACEPIECE/HALF MASK AIR-PURIFYING
CARTRIDGE RESP W/PARTICULATE FILTERS. WEAR CHEM GOG IF A HALF MASK
IS WORN. FOR SM SPILLS: SWEE P UP & DISPOSE OF IN DOT-APPRVD WASTE
(SUPP DATA)
Neutralizing Agent:NONE SPECIFIED BY MANUFACTURER.

========== Handling and Storage ==========

Handling and Storage Precautions:STORE IN A COOL/DRY/WELL-VENTD PLACE
AWAY FROM INCOMPATIBLE MATLS. KEEP BAGS/FIBER DRUMS DRY @ ALL
TIMES. DO NOT GET IN EYES, ON SKIN/CLTHG.
Other Precautions:DO NOT CUT/GRIND/WELD/DRILL ON/NEAR CONTR. CONTRS,
EVEN THOSE THAT HAVE BEEN EMPTIED, WILL RETAIN PROD RESIDUE. ALWAYS
OBEY HAZ WARNINGS & HNDLE EMPTY CONTRS AS IF THEY WERE FULL.
CELLULOSE ETHERS ARE H*2O SOL POLYMERS WHICH FORM(SUPP DATA)

========== Exposure Controls/Personal Protection ==========

Respiratory Protection:IF USE CNDTNS GENERATE DUST, WEAR A NIOSH/MSHA APPRVD RESP APPROP FOR THOSE EMMISION LEVELS. APPROP RESP MAY BE A NIOSH/MSHA APPRVD: FULL FACEPIECE/HALF MASK AIR-PURIFYING CARTRIDGE RESP W/PARTICULATE FILTERS, A SCBA IN PRESS (ING 3)
Ventilation:GENERAL ROOM VENTILATION.
Protective Gloves:IMPERVIOUS GLOVES .
Eye Protection:CHEMICAL WORKERS GOGGLES .
Other Protective Equipment:AN EYEWASH & SFTY SHOWER SHOULD BE NEARBY AND READY FOR USE. LONG-SLEEVED SHIRT, & TROUSERS.
Work Hygienic Practices:WASH THOROUGHLY AFTER HANDLING.
Supplemental Safety and Health
EXPLO HAZ: CONC IS 0.03 OZ/CU FT. SPILL PROC: CONTRS. FOR LG SPILLS, SHOVEL INTO DOT-APPRVD WASTE CONTRS. KEEP OUT OF SEWERS/STORM DRAINS/SURF WATERS, & SOIL. COMPLY W/ALL APPLIC GOVT REGS ON SPILL RP TD & HNDLG & DISP OF WASTE. OTHER PREC:AQUEOUS DISPERSIONS BY SWELLING & BY SUCCESSIVE HYDRATION OF THEIR (ING 3)

========== Physical/Chemical Properties ==========

Solubility in Water:SLIGHT
Appearance and Odor:WHITE TO OFF-WHITE FREE FLOWING POWDER; ODORLESS.

========== Stability and Reactivity Data ==========

Stability Indicator/Materials to Avoid:YES
OXIDIZING MATERIALS.
Stability Condition to Avoid:HEAT, SPARKS, AND OPEN FLAMES. AVOID DUST CLOUDS OR LAYERS.
Hazardous Decomposition Products:MAY LIBERATE CO OR CO*2.

========== Disposal Considerations ==========

Waste Disposal Methods:DISPOSE OF CONTAMD PROD & MATLS USED IN CLEANING UP SPILLS/LEAKS IN MANNER APPRVD FOR MATL. CONSULT APPROP FED/ST/LOC REGULATORY AGENCIES TO ASCERTAIN PROPER DISP PROC. NOTE:EMPTY CONTRS CAN HAVE RESI DUES, GASES, MISTS & ARE SUBJECT TO PROPER (ING 4)

ScienceLab.com
Chemicals & Laboratory Equipment

Health	1
Fire	0
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Sodium chloride (Rock Salt) MSDS

Section 1: Chemical Product and Company Identification

Product Name: Sodium chloride (Rock Salt)

Catalog Codes: SLS2299

CAS#: 7647-14-5

RTECS: VZ4725000

TSCA: TSCA 8(b) inventory: Sodium chloride

CI#: Not applicable.

Synonym: Salt; Sea Salt

Chemical Name: Sodium chloride

Chemical Formula: NaCl

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: 1-800-901-7247
International Sales: 1-281-441-4400

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Sodium chloride	7647-14-5	100

Toxicological Data on Ingredients: Sodium chloride: ORAL (LD50): Acute: 3000 mg/kg [Rat.]. 4000 mg/kg [Mouse]. DERMAL (LD50): Acute: >10000 mg/kg [Rabbit]. DUST (LC50): Acute: >42000 mg/m 1 hours [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Not applicable.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: Not applicable.

Special Remarks on Fire Hazards: When heated to decomposition it emits toxic fumes.

Special Remarks on Explosion Hazards:
Electrolysis of sodium chloride in presence of nitrogenous compounds to produce chlorine may lead to formation of explosive nitrogen trichloride. Potentially explosive reaction with dichloromaleic anhydride + urea.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep locked up.. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, acids.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Hygroscopic

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Solid crystalline powder.)

Odor: Slight.

Taste: Saline.

Molecular Weight: 58.44 g/mole

Color: White.

pH (1% soln/water): 7 [Neutral.]

Boiling Point: 1413°C (2575.4°F)

Melting Point: 801°C (1473.8°F)

Critical Temperature: Not available.

Specific Gravity: 2.165 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility:
Easily soluble in cold water, hot water. Soluble in glycerol, and ammonia. Very slightly soluble in alcohol. Insoluble in Hydrochloric Acid.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials, high temperatures.

Incompatibility with various substances: Reactive with oxidizing agents, metals, acids.

Corrosivity: Not considered to be corrosive for metals and glass.

Special Remarks on Reactivity:
Hygroscopic. Reacts with most nonnoble metals such as iron or steel, building materials (such as cement) Sodium chloride is rapidly attacked by bromine trifluoride. Violent reaction with lithium.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
WARNING: THE LC50 VALUES HEREUNDER ARE ESTIMATED ON THE BASIS OF A 4-HOUR EXPOSURE. Acute oral toxicity (LD50): 3000 mg/kg [Rat.]. Acute dermal toxicity (LD50): >10000 mg/kg [Rabbit]. Acute toxicity of the dust (LC50): >42000 mg/m3 1 hours [Rat].

Chronic Effects on Humans: MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Lowest Published Lethal Dose (LDL) [Man] - Route: Oral; Dose: 1000 mg/kg

Special Remarks on Chronic Effects on Humans:
Causes adverse reproductive effects in humans (fetotoxicity, abortion,) by intraplacental route. High intake of sodium chloride, whether from occupational exposure or in the diet, may increase risk of TOXEMIA OF PREGNANCY in susceptible women (Bishop, 1978). Hypertonic sodium chloride solutions have been used to induce abortion in late pregnancy by direct infusion into the uterus (Brown et al, 1972), but this route of administration is not relevant to occupational exposures. May cause adverse reproductive effects and birth defects in animals, particularly rats and mice (fetotoxicity, abortion, musculoskeletal abnormalities, and maternal effects (effects on ovaries, fallopian tubes) by oral, intraperitoneal, intraplacental, intrauterine, parenteral, and subcutaneous routes. While sodium chloride has been used as a negative control n some reproductive studies, it has also been used as an example that almost any chemical can cause birth defects in experimental animals if studied under the right conditions (Nishimura & Miyamoto, 1969). In experimental animals, sodium chloride has caused delayed effects on newborns, has been fetotoxic, and has caused birth defects and abortions in rats and mice (RTECS, 1997). May affect genetic material (mutagenic)

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: Causes eye irritation. Ingestion: Ingestion of large quantities can irritate the stomach (as in overuse of salt tablets) with nausea and vomiting. May affect behavior (muscle spasicity/contraction, somnolence), sense organs, metabolism, and cardiovascular system. Continued exposure may produce dehydration, internal organ congestion, and coma. Inhalation: Material is irritating to mucous membranes and upper respiratory tract.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Sodium chloride (Rock Salt)

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
R40- Possible risks of irreversible effects. S24/25- Avoid contact with skin and eyes.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 0

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles.

Section 16: Other Information

References:
-Hawley, G.G.. The Condensed Chemical Dictionary, 11e ed., New York N.Y., Van Nostrand Reinold, 1987. -SAX, N.I. Dangerous Properties of Industrial Materials. Toronto, Van Nostrand Reinold, 6e ed. 1984. -The Sigma-Aldrich Library of Chemical Safety Data, Edition II.

Other Special Considerations: Not available.

Created: 10/09/2005 06:30 PM

Last Updated: 11/01/2010 12:00 PM

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Rhodia

Material Safety Data Sheet

RHODAPEX CO-436

Date Prepared: 8/16/07 Supersedes Date: 12/28/04

1. PRODUCT AND COMPANY DESCRIPTION

RHODIA INC.
RHODIA NOVECARE
CN 7500
8 Cedar Brook Drive
Cranbury NJ 08512-7500

Emergency Phone Numbers:
FOR EMERGENCIES INVOLVING A SPILL, LEAK, FIRE, EXPOSURE OR ACCIDENT CONTACT: CHEMTREC (800-424-9300 within the United States or 703-527-3887 for international collect calls) or Rhodia CAERS (Communication and Emergency Response System) at 800-916-3232.

For Product Information:
(800) 973-7873

Chemical Name or Synonym:
BLEND OF ANIONIC SURFACTANT / SOLVENT

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS Reg Number	OSHA Hazard	Percentage
AMMONIUM NONYLPHENOL ETHER SULFATE, BRANCHED	68649-55-8	Y	~ 60
ETHANOL	64-17-5	Y	~ 15
WATER	7732-18-5	N	~ 25
ETHOXYLATED NONYLPHENOL, BRANCHED	68412-54-4	Y	~ 3

3. HAZARDS IDENTIFICATION

A. EMERGENCY OVERVIEW:

Physical Appearance and Odor:

clear / liquid, alcohol-like odor.

Warning Statements:
WARNING!! FLAMMABLE LIQUID. SEVERE EYE IRRITANT. SKIN IRRITANT.

B. POTENTIAL HEALTH EFFECTS:

Acute Eye:
Severe irritant. Can cause redness, irritation.

Acute Skin:
Low acute dermal toxicity. Irritant. Can cause redness, inflammation, irritation.

Acute Inhalation:
Low acute inhalation toxicity. Mists may cause drowsiness, dizziness, headache, depression, upper respiratory tract irritation.

Acute Ingestion:
Practically non-toxic.

Chronic Effects:
This product does not contain any ingredient designated by IARC, NTP, ACGIH or OSHA as probable or suspected human carcinogens.

4. FIRST AID MEASURES

FIRST AID MEASURES FOR ACCIDENTAL:

Eye Exposure:
Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Seek medical attention.

Skin Exposure:
In case of contact, immediately wash with plenty of soap and water for at least 5 minutes. Seek medical attention. Remove contaminated clothing and shoes. Clean contaminated clothing and shoes before re-use.

Inhalation:
If respiratory irritation or distress occurs remove victim to fresh air. Seek medical attention if respiratory irritation or distress continues.

Ingestion:
If victim is conscious and alert, give 1-2 glasses of water to drink. Do not give anything by mouth to an unconscious person. Seek medical attention. Do not leave victim unattended.

MEDICAL CONDITIONS POSSIBLY AGGRAVATED BY EXPOSURE:
Skin contact may aggravate existing skin disease.

NOTES TO PHYSICIAN:
All treatments should be based on observed signs and symptoms of distress in the patient.

Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Treat symptomatically. No specific antidote available.

5. FIRE FIGHTING MEASURES

FIRE HAZARD DATA:

Flash Point:
28 C (82 F). Flammability Class: FLAMMABLE.

Method Used:
Closed cup

Flammability Limits (vol/vol%): **Lower:** 3.3 **Upper:** 19

Extinguishing Media:
Recommended: dry chemical, carbon dioxide, foam.

Special Fire Fighting Procedures:
Firefighters should wear NIOSH/MSHA approved self-contained breathing apparatus and full protective clothing.

Unusual Fire and Explosion Hazards:
Product will burn under fire conditions. Vapors may travel a considerable distance to a source of ignition and flash back along vapor trail. Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.

Hazardous Decomposition Materials (Under Fire Conditions):
oxides of nitrogen
oxides of sulfur
oxides of carbon

6. ACCIDENTAL RELEASE MEASURES

Evacuation Procedures and Safety:
Wear appropriate protective gear for the situation. See Personal Protection information in Section 8.

Containment of Spill:
Follow procedure described below under Cleanup and Disposal of Spill.

Cleanup and Disposal of Spill:
Absorb with an inert absorbent. Shovel up into an appropriate closed container (see Section 7: Handling and Storage).

Environmental and Regulatory Reporting:
Do not flush to drain. Spills may be reportable to the National Response Center (800-424-8802) and to state and/or local agencies.

7. HANDLING AND STORAGE

Minimum/Maximum Storage Temperatures:
> 4 C (39 F)

Handling:
Avoid breathing vapors and mists. Avoid direct or prolonged contact with skin and eyes. Use nonsparking tools and grounded/bonded equipment and containers when transferring. DO NOT ALLOW TO FREEZE.

Ethylene oxide may collect in container head space. Although concentrations are expected to remain below established exposure limits, provide adequate ventilation when accessing or working with open containers and tanks.

Storage:
SHIP AND STORE ABOVE 40F. Store in tightly closed containers. Store in an area that is dry, well-ventilated, away from ignition sources, away from incompatible materials (see Section 10, Stability and Reactivity).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Introductory Remarks:
These recommendations provide general guidance for handling this product. Because specific work environments and material handling practices vary, safety procedures should be developed for each intended application. While developing safe handling procedures, do not overlook the need to clean equipment and piping systems for maintenance and repairs. Waste resulting from these procedures should be handled in accordance with Section 13: Disposal Considerations.

Assistance with selection, use and maintenance of worker protection equipment is generally available from equipment manufacturers.

Exposure Guidelines:
Exposure limits represent regulated or recommended worker breathing zone concentrations measured by validated sampling and analytical methods, meeting the regulatory requirements. The following limits apply to this material, where, if indicated, S=skin and C=ceiling limit:

ETHANOL

	Notes	TWA	STEL
ACGIH		1000 ppm	
OSHA		1000 ppm	
OSHA		1900 mg/cu m	

Engineering Controls:
Where engineering controls are indicated by use conditions or a potential for excessive exposure exists, the following traditional exposure control techniques may be used to effectively minimize employee exposures: general area dilution/exhaust ventilation.

Respiratory Protection:
When respirators are required, select NIOSH/MSHA approved equipment based on actual or potential airborne concentrations and in accordance with the appropriate regulatory standards and/or industrial recommendations.

For reasonably foreseeable industrial end uses of this material, respiratory protection should not be necessary.

Eye/Face Protection:
Eye and face protection requirements will vary dependent upon work environment conditions and material handling practices. Appropriate ANSI Z87 approved equipment should be selected for the particular use intended for this material.

Eye contact should be prevented through use of chemical safety glasses with side shields or splash proof goggles. An emergency eye wash must be readily accessible to the work area.

Skin Protection:
Skin contact should be minimized through use of gloves and suitable long-sleeved clothing (i.e., shirts and pants). Consideration must be given both to durability as well as permeation resistance.

Work Practice Controls:
Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when working with or handling this material:

(1) Do not store, use, and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored.
(2) Wash hands and face carefully before eating, drinking, using tobacco, applying cosmetics, or using the toilet.
(3) Wash exposed skin promptly to remove accidental splashes or contact with this material.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical properties here represent typical properties of this product. Contact the business area using the Product Information phone number in Section 1 for its exact specifications.

Physical Appearance:
clear / liquid.

Odor:
alcohol-like odor.

pH:

6.5 to 7.5 at 10 w/wt%.

Specific Gravity:
1.065 at 25 C (77 F).

Water Solubility:
soluble

Melting Point Range:
Not Available

Freezing Point Range:
< 0 C (32 F)

Boiling Point Range:
85 C (185 F) at 760 mmHg

Vapor Pressure:
< 25 mmHg at 25 C (77 F)

Vapor Density:
Not Available

Percent Volatiles by Volume:
40

Viscosity:
viscosity (centipoises) : < 500 cps at 25 C (77 F).

10. STABILITY AND REACTIVITY

Chemical Stability:
This material is stable under normal handling and storage conditions described in Section 7.

Conditions To Be Avoided:
extreme cold
heat
open flame
spark
static electricity

Materials/Chemicals To Be Avoided:
strong oxidizing agents
strong reducing agents

The Following Hazardous Decomposition Products Might Be Expected:

Decomposition Type: thermal
oxides of nitrogen
oxides of sulfur

oxides of carbon

Hazardous Polymerization Will Not Occur.

Avoid The Following To Inhibit Hazardous Polymerization:
not applicable

11. TOXICOLOGICAL INFORMATION

Acute Eye Irritation:
Toxicological Information and Interpretation:
eye - eye irritation, rabbit. Severely irritating.

Acute Skin Irritation:
Toxicological Information and Interpretation:
skin - skin irritation, rabbit. Moderately irritating.

Acute Dermal Toxicity:
No test data found for product.

Acute Respiratory Irritation:
No test data found for product.

Acute Inhalation Toxicity:
No test data found for product.

Acute Oral Toxicity:
No test data found for product.

Chronic Toxicity:
This product does not contain any substances that are considered by OSHA, NTP, IARC or ACGIH to be "probable" or "suspected" human carcinogens.

No additional test data found for product.

12. ECOLOGICAL INFORMATION

Ecotoxicological Information:
No data found for product.

Chemical Fate Information:
No data found for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method:
Chemical additions, processing or otherwise altering this material may make the waste management information presented in this MSDS incomplete, inaccurate or otherwise inappropriate. Please be advised that state and local requirements for waste disposal may be more restrictive or otherwise different from federal laws and regulations. Consult state and local regulations regarding the proper disposal of this material.

Container Handling and Disposal:
Any containers or equipment used should be decontaminated immediately after use.

EPA Hazardous Waste - YES

EPA RCRA HAZARDOUS WASTE CODES:
'I' Ignitable.

14. TRANSPORTATION INFORMATION

Transportation Status: IMPORTANT! Statements below provide additional data on listed DOT classification.
The listed Transportation Classification does not address regulatory variations due to changes in package size, mode of shipment or other regulatory descriptors.

US Department of Transportation
Hazard Class..... 3
Shipping Name:
ETHANOL SOLUTION
ID Number..... UN1170
Packing Group.... III
Labels..... FLAMMABLE LIQUID
Emergency Guide #.... 127

15. REGULATORY INFORMATION

Inventory Status

Inventory	Status
UNITED STATES (TSCA)	Y
CANADA (DSL)	Y
EUROPE (EINECS/ELINCS)	P
AUSTRALIA (AICS)	Y
JAPAN (MITI)	Y
SOUTH KOREA (KECL)	Y

Y = All ingredients are on the inventory.

E = All ingredients are on the inventory or exempt from listing.
P = One or more ingredients fall under the polymer exemption or are on the no longer polymer list. All other ingredients are on the inventory or exempt from listing.
N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing.

FEDERAL REGULATIONS

Inventory Issues:
All functional components of this product are listed on the TSCA Inventory.

SARA Title III Hazard Classes:

Fire Hazard	- YES
Reactive Hazard	- NO
Release of Pressure	- NO
Acute Health Hazard	- YES
Chronic Health Hazard	- NO

SARA 313 Chemicals
GLYCOL ETHERS (21.0%)

OTHER FEDERAL REGULATIONS:

FDA Status:
This product meets the compositional requirements of:
21 CFR 178.3400 EMULSIFIERS AND/OR SURFACE ACTIVE AGENTS

STATE REGULATIONS:
This product contains the following components that are regulated under California Proposition 65:

Ingredient Name	Cancer List	Reprod. List	No Sign. Risk Lvl (ug/day) California	RPI
DIOXANE	Y	N	30	ND
ETHYLENE OXIDE	Y	Y	2	ND

16. OTHER INFORMATION

National Fire Protection Association Hazard Ratings--NFPA(R):

2 Health Hazard Rating--Moderate
3 Flammability Rating--Serious
0 Instability Rating--Minimal

National Paint & Coating Hazardous Materials Identification System--HMIS(R):

2 Health Hazard Rating--Moderate
3 Flammability Rating--Serious
0 Reactivity Rating--Minimal

Reason for Revisions:
Change and/or addition made to Section 2, Regulatory Review and Update.

Key Legend Information:
ACGIH - American Conference of Governmental Industrial Hygienists
OSHA - Occupational Safety and Health Administration
TLV - Threshold Limit Value
PEL - Permissable Exposure Limit
TWA - Time Weighted Average
STEL - Short Term Exposure Limit
NTP - National Toxicology Program
IARC - International Agency for Research on Cancer
ND - Not determined
RHODIA - Rhodia Established Exposure Limits

Disclaimer:
The information herein is given in good faith but no warranty, expressed or implied, is made.

**** End of MSDS Document ****

COVIDIEN
Mallinckrodt

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

Trade name of the substance	ACETAMINOPHEN
Identification Number	103-90-2
Registration number	-
Synonyms	APAP * PARACETAMOL * 4-HYDROXYACETANILIDE * N-(4-HYDROXYPHENYL) ACETAMIDE
Product Codes	Mallinckrodt: 0044, 0046, 0048, 0057, 0077, 0081, 0084, 0167, 0169, 0422, 0894, 0895, 0896, 0935, 1125, 1617, 1634, 1680, 3065, 3477, 4814, 4864, 5541, 5542, 5543, 6088, 6135, 6375, 7250, 7325, 7375, 7580, 7845
Date of first issue	30-October-2009
Version number	03
Revision date	15-December-2010
Supersedes date	07-November-2010

Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medication: Analgesic agent.
Uses advised against	None known.

Details of the supplier of the safety data sheet

Manufacturer

Company name	Covidien (Mallinckrodt)
Address	Mallinckrodt Chemical Limited Hall Lane, Staveley, Chesterfield, Derbyshire S43 3RW UK
Customer Service	+44 1246 561 200
Emergency telephone number	1-703-527-3887
SDS number	ACEPH
Reference number	Not available.

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Classification	Xn;R58/20/22-48/20/22

The full text for all R-phrases is displayed in section 16.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Acute toxicity, oral	Category 4	Harmful if swallowed.
Acute toxicity, inhalation	Category 4	Harmful if inhaled.
Specific target organ toxicity - single exposure	Category 2	May cause damage to organs.
Specific target organ toxicity - repeated exposure	Category 2	May cause damage to organs through prolonged or repeated exposure.

Hazard summary

Physical hazards	Not classified for physical hazards.

Health hazards	Harmful by inhalation and if swallowed. Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. Harmful: possible risk of irreversible effects through inhalation and if swallowed. Occupational exposure to the substance or mixture may cause adverse health effects.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. Danger of serious damage to health by prolonged exposure. May cause damage to the liver and kidneys. For additional information on inhalation hazards, see Section 11 of this safety data sheet.
Main symptoms	Irritation of eyes and mucous membranes. Rash. Skin irritation. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains:	ACETAMINOPHEN
Identification Number	103-90-2

Signal word	Warning
Hazard statements	Harmful if swallowed. Harmful if inhaled. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure. Dust may form explosive mixture with air.

Precautionary statements

Prevention	Use only outdoors or in a well-ventilated area. Do not breathe dust. Do no eat, drink or smoke when using this product. Wash thoroughly after handling. Dust accumulation from this product may present an explosion hazard in the presence of an ignition source.
Response	IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information

Other hazards Not assigned.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ACETAMINOPHEN	100	103-90-2 203-157-5	-	-	#
Classification:	DSD:	Xn;R68/20/22-48/20/22			
	CLP:	Acute Tox. 4;H302, Acute Tox. 4;H332, STOT SE 2;H371, STOT RE 2;H373			

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC. #: This substance has workplace exposure limit(s).

Composition comments The full text for all R-phrases is displayed in Section 16. The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: FIRST AID MEASURES

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation.

Description of first aid measures

Inhalation If gas/fume/vapour/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. Get medical attention if symptoms persist.

Skin contact	Rinse skin with water/shower. Remove contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Do not induce vomiting without medical advice. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Rinse mouth. Get medical attention if any discomfort continues.
Most important symptoms and effects, both acute and delayed	Not available.
Indication of any immediate medical attention and special treatment needed	Oxygen, if needed. Keep victim under observation.

SECTION 5: FIREFIGHTING MEASURES

General fire hazards	Not available.
Extinguishing media	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Not available.
Special hazards arising from the substance or mixture	Dust may form explosive mixture with air. Fire may produce irritating, corrosive and/or toxic gases.
Advice for firefighters	
Special protective equipment for firefighters	Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask.
Special firefighting procedures	In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Ventilate the area. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them.
For emergency responders	Not available.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not contaminate water.
Methods and material for containment and cleaning up	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Should not be released into the environment. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. For waste disposal, see section 13.
Reference to other sections	Not available.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling	DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Minimise dust generation and accumulation. Keep formation of airborne dusts to a minimum. Dust may form explosive mixture with air. Provide appropriate exhaust ventilation at places where dust is formed. In case of insufficient ventilation, wear suitable respiratory equipment. Take precautionary measures against static discharges. Static electricity and formation of sparks must be prevented. All equipment used when handling the product must be grounded. Ground and bond containers when transferring material. Use non-sparking tools and explosion-proof equipment. Do not breathe dust. Avoid contact with eyes. Avoid prolonged exposure. Wash thoroughly after handling. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Store in a well-ventilated place. Keep container tightly closed. Guard against dust accumulation of this material. This material can accumulate static charge which may cause spark and become an ignition source. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Keep away from heat, sparks and open flame. Keep at temperature not exceeding 40°C. Use care in handling/storage.

Specific end use(s) Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational exposure limits

Ireland

Material	Type	Value	Form
ACETAMINOPHEN (103-90-2)	TWA	10.0000 mg/m3	Total inhalable dust.

United Kingdom

Material	Type	Value	Form
ACETAMINOPHEN (103-90-2)	TWA	10.0000 mg/m3	Inhalable dust.

Biological limit values

United Kingdom

Material	Type	Value	Form
ACETAMINOPHEN (103-90-2)	TWA	10.0000 mg/m3	Inhalable dust.

Recommended monitoring procedures Not available.

Exposure controls

Exposure limit values

Mallinckrodt

Material	Type	Value
ACETAMINOPHEN (103-90-2)	TWA	5.0000 mg/m3

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL, suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

General information Use personal protective equipment as required. Keep working clothes separately.

Eye/face protection Chemical goggles are recommended. Provide eyewash station and safety shower. Avoid contact with eyes.

Skin protection

- Hand protection Wear protective gloves.

- Other Avoid contact with the skin. Wear suitable protective clothing.

Respiratory protection If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection. Wear respirator with dust filter.

Thermal hazards Not available.

Hygiene measures When using, do not eat, drink or smoke. Do not breathe dust. Avoid contact with eyes. Avoid contact with skin. Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance Powder. Granular.

Physical state Solid.

Form Powder.

Colour	White.
Odour	Odourless.
Odour threshold	Not available.
pH	5,5 - 6,5 Saturated solution in water
Melting point/freezing point	169 - 170,5 °C (336,2 - 339,8 °F)
Boiling point, initial boiling point, and boiling range	Not available.
Flash point	Not applicable.
Auto-ignition temperature	Not applicable.
Flammability (solid, gas)	Not available.
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Oxidising properties	Not applicable.
Explosive properties	Not applicable.
Explosive limit	Not applicable.
Vapour pressure	0 kPa at 25°C
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Relative density	Not available.
Density	1,2929 g/cm3 estimated
Solubility	Not available.
Partition coefficient (n-octanol/water)	Not available.
Decomposition temperature	Not available.
Bulk density	Not applicable.
Pour point	Not applicable.
Viscosity	Not available.
VOC (Weight %)	Not available.
Percent volatile	Not available.
Other data	
Molecular formula	C8-H9-N-O2
Molecular weight	151,16 g/mol
Other information	No relevant additional information available.
Dust Electrostatic Properties	
Charge Relaxation Time at Ambient Humidity	1,4 hours
Charge Relaxation Time at Low Humidity	5,5 hours
Minimum Ignition Energy (Cloud)	5 - 10 mJ
Resistivity at Ambient Humidity	8,5e+13 ohm.m
Resistivity at Low Humidity	8,5e+14 ohm.m
Dust explosion properties	
dP/dT	843 bar/s
Kst	229 bar.m/s
Limiting Oxygen Concentration	10 - 11 %

Minimum Explosible Concentration	50 - 60 g/m³
Minimum Ignition Temperature-Cloud	550 °C (1094 °F)
Minimum Ignition Temperature-Layer	> 400 °C (> 752 °F)
Pmax	8,7 bar

SECTION 10: STABILITY AND REACTIVITY

Reactivity	None known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Not available.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	Acids. Amides.
Hazardous decomposition products	Toxic gas. Carbon oxides. Nitrogen oxides (NOx). In the presence of heat and water, substance may hydrolyze to acetic acid and p-aminophenol.

SECTION 11: TOXICOLOGICAL INFORMATION

General information Not available.

Information on likely routes of exposure

Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Inhalation	Inhalation of dusts may cause respiratory irritation.
Skin contact	May cause skin irritation.
Eye contact	Contact with eyes may cause irritation. Dust or powder may irritate eye tissue.

Symptoms Not available.

Information on toxicological effects

Acute toxicity Not available.

Product	Test results
ACETAMINOPHEN (103-90-2)	Acute Oral LD50 Mouse: 338 mg/kg Acute Oral LD50 Rat: 2400 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Respiratory sensitization	Not available.
Skin sensitization	Not available.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Not classified.

IARC Monographs. Overall Evaluation of Carcinogenicity

ACETAMINOPHEN (CAS 103-90-2) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Liver. Kidneys.
Specific target organ toxicity - repeated exposure	Liver.
Aspiration hazard	Not available.
Mixture versus substance information	Not available.
Other information	Not available.

Minimum Explosible Concentration	50 - 60 g/m³
Minimum Ignition Temperature-Cloud	590 °C (1094 °F)
Minimum Ignition Temperature-Layer	> 400 °C (> 752 °F)
Pmax	8,7 bar

SECTION 10: STABILITY AND REACTIVITY

Reactivity	None known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Not available.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	Acids. Amides.
Hazardous decomposition products	Toxic gas. Carbon oxides. Nitrogen oxides (NOx). In the presence of heat and water, substance may hydrolyze to acetic acid and p-aminophenol.

SECTION 11: TOXICOLOGICAL INFORMATION

General information	Not available.
Information on likely routes of exposure	
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Inhalation	Inhalation of dusts may cause respiratory irritation.
Skin contact	May cause skin irritation.
Eye contact	Contact with eyes may cause irritation. Dust or powder may irritate eye tissue.
Symptoms	Not available.
Information on toxicological effects	
Acute toxicity	Not available.

Product	Test results
ACETAMINOPHEN (103-90-2)	Acute Oral LD50 Mouse: 338 mg/kg Acute Oral LD50 Rat: 2400 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Respiratory sensitization	Not available.
Skin sensitization	Not available.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Not classified.
IARC Monographs. Overall Evaluation of Carcinogenicity	
ACETAMINOPHEN (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Liver. Kidneys.
Specific target organ toxicity - repeated exposure	Liver.
Aspiration hazard	Not available.
Mixture versus substance information	Not available.
Other information	Not available.

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Product	Test results
ACETAMINOPHEN (103-90-2)	EC50 Water flea (Daphnia magna): 6,1 - 14 mg/l 48.00 hours LC50 Fathead minnow (Pimephales promelas): 814 mg/l 96.00 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility	Not available.
Environmental fate - Partition coefficient	Not available.
Mobility in soil	Not available.
Results of PBT and vPvB assessment	Not available.
Other adverse effects	Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Residual waste	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used. The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not discharge into drains, water courses or onto the ground. Do not dispose of waste into sewer.

SECTION 14: TRANSPORT INFORMATION

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1
Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2
Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3
Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V
Not listed.
Directive 96/61/EC concerning integrated pollution prevention and control (IPPC): Article 16, European Pollution Emission Registery (EPER)
Not listed.
Regulation (EC) No. 1907/2006, Article 59(1). Candidate List
Not listed.

Other regulations	This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The product is classified and labelled in accordance with EC directives or respective national laws.
National regulations	Not available.
Chemical safety assessment	Not available.

SECTION 16: OTHER INFORMATION

List of abbreviations	Not available.
References	Not available.
Information on evaluation method leading to the classification of mixture	Not available.
Full text of any statements or R-phrases and H-phrases under Sections 2 to 16	R20/22 Harmful by inhalation and if swallowed. R48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. R68/20/22 Harmful: possible risk of irreversible effects through inhalation and if swallowed. H302 - Harmful if swallowed. H332 - Harmful if inhaled. H371 - May cause damage to organs. H373 - May cause damage to organs through prolonged or repeated exposure.
Revision information	Product and Company Identification: Product and Company Identification
Training information	Not available.
Disclaimer	Mallinckrodt (D/B/A Covidien) provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.
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Revision date	15-December-2010
Print date	15-December-2010

ScienceLab.com
Chemicals & Laboratory Equipment

Health	1
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Pentoxifylline MSDS

Section 1: Chemical Product and Company Identification

Product Name: Pentoxifylline

Catalog Codes: SLP1726, SLP3535

CAS#: 6493-05-6

RTECS: XH2475000

TSCA: TSCA 8(b) inventory: No products were found.

CI#: Not available.

Synonym: Dimethyloxohexyltxanthine, Oxpentifylline, Pentoxifyllin, Pentoxiphyllium, Pentoxyphylline, Trental, Vazoflirin; 1-(5-Oxohexyl)-3,7-dimethylxanthine; 1-(5-Oxyhexyl)theobromine; 1H-PPUrine-2,6-dione, 3,7-dihydro-3,7-dimethyl-1-(5-oxohexyl)- (9CI); 3,7-Dihydro-3,7-dimethyl-1-(5-oxohexyl)-1H-purine-2,6-dione; 3,7-Dimethyl-1-(5-oxohexyl)-1H,3H-purin-2,6-dione; 3,7-Dimethyl-1-(5-oxohexyl)xanthine

Chemical Name: Theobromine, 1-(5-oxohexyl)-

Chemical Formula: C13-H18-N4-O3

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Pentoxifylline	6493-05-6	100

Toxicological Data on Ingredients: Pentoxifylline: ORAL (LD50): Acute: 1170 mg/kg [Rat]. 1225 mg/kg [Mouse].

Section 3: Hazards Identification

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. The substance may be toxic to blood, liver, skin. Repeated or prolonged exposure to the substance can produce target organs damage.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...).

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards:
When heated to decomposition it emits toxic fumes. As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid.

Odor: Not available.

Taste: Not available.

Molecular Weight: Not available.

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: 105°C (221°F)

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility:
Soluble in cold water, hot water. Soluble in Benzene

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 1170 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: blood, liver, skin.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:
May cause adverse reproductive effects and birth defects (teratogenic) based on animal test data. May affect genetic material (mutagenic). Excreted in maternal milk in human.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation. Ingestion: Harmful if swallowed. May cause gastrointestinal tract irritation/disturbances. May affect the cardiovascular system (hypotension, cardiac arrhythmias, agina, palpitations, bradycardia, antrioventricular block), respiration (respiratory depression), behavior/central nervous system (convulsions, headache, tremors, dizziness, drowsiness, agitation), and liver Chronic Potential Health Effects: Skin: Prolonged or repeated skin contact may cause dermatitis. Ingestion: Prolonged or repeated ingestion may affect behavior/central nervous system, and blood (blood dyscrasias), and liver (hepatitis, jaundice).

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: No products were found.

Other Regulations:
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
R22- Harmful if swallowed. S36- Wear suitable protective clothing.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

Section 16: Other Information

References:
-The Sigma-Aldrich Library of Chemical Safety Data, Edition II. Martindale, The Extra Pharmacopoeia, 29th edition,1989. Manufacturer's Material Safety Data Sheet.

Other Special Considerations: Not available.

Created: 10/11/2005 01:39 PM

Last Updated: 11/01/2010 12:00 PM

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Clariant

Safety data sheet in accordance with 2001/58/EC

POLYGLYKOL 1000

Substance key: SXR024808
Version : 1 - 23 / EU

Revision Date: 31.10.2005
Date of printing : 27.08.2007

1. Identification of the substance/preparation and company

Trade name
POLYGLYKOL 1000

Use of the substance/preparation.
Industry sector : Personal Care
Type of use : Techno-chemical industry.
Cosmetic
Pharma

Identification of the company
Clariant Produkte (Deutschland) GmbH

65926 Frankfurt am Main
Telephone no. : +49 69 305 18000

Information about the substance/preparation
Division Functional Chemicals
++49(0)69-305-2092/15315/32251

Emergency telephone number : +49 69 305 6418

2. Composition/information on ingredients

Chemical characterization
polyethylene glycol, HO-(CH2-CH2-O)n-H, average molecular mass 1000

INCI name
PEG-20

CAS number : 25322-68-3

3. Hazards identification

No particular hazards known.

4. First aid measures

General information
Remove soiled or soaked clothing immediately

After inhalation
When inhaled remove to fresh air and seek medical aid.

After contact with skin
In case of contact with skin wash off with warm water

After contact with eyes
In case of contact with eyes rinse thoroughly with water

After ingestion
Summon a doctor immediately.

Clariant

Safety data sheet in accordance with 2001/58/EC
POLYGLYKOL 1000

Substance key: SXR024808
Version : 1 - 23 / EU

Revision Date: 31.10.2005
Date of printing : 27.08.2007

5. Fire-fighting measures

Suitable extinguishing media
water spray jet
dry powder
foam
carbon dioxide

Special hazards from the substance itself, its combustion products or from its vapours
In case of fires, hazardous combustion gases are formed: Carbon monoxide (CO)

Special protective equipment for firefighting
Use self-contained breathing apparatus

6. Accidental release measures

Personal precautions
Wear suitable personal protective equipment.
Avoid dust formation.
Ensure adequate ventilation.

Environmental precautions
Do not allow to enter drains or waterways

Methods for cleaning up/taking up
Take up mechanically
Dilute with plenty of water

7. Handling and storage

Advice on safe handling
Avoid the formation and deposition of dust.
Provide good ventilation of working area (local exhaust ventilation if necessary).

Further information on storage conditions
Keep container tightly closed and dry in a cool, well-ventilated place
Do not keep at temperatures above 30 °C.
Recommended storage temperature: 10 - 25 °C.

8. Exposure controls/personal protection

General protective measures
Avoid contact with eyes and skin
Do not inhale dust

Hygiene measures
Observe the usual precautions when handling chemicals.

Respiratory protection : Use respiratory protection in case of insufficient exhaust ventilation or prolonged exposure
Particle-filtering half-mask according to DIN EN 149
Filter class FFP2

Hand protection :	Chemical resistant gloves according to category III of DIN EN 374 Minimum thickness (glove): not determined With solid dry substances permeation is not to be expected, therefore the breakthrough-time for this protective glove has not been measured. These types of protective gloves are offered by various manufacturers. Please note the manufacturers' detailed statements, especially about the minimum thickness and the minimum breakthrough time. Consider also the particular working conditions under which the gloves are being used.
Eye protection :	safety glasses

9. Physical and chemical properties

Form :	Waxy type
Colour :	white
Odour :	characteristic
Freezing point :	35 - 40 °C
Boiling temperature :	not determined
Flash point :	270 °C Method : DIN 51376 (open cup)
Ignition temperature :	> 320 °C Method : DIN 51794
Oxidizing properties :	not determined
Self-ignition temperature :	not determined
Lower explosion limit :	Not applicable
Upper explosion limit :	Not applicable
Evaporation rate :	Not applicable
Vapour pressure :	< 0,1 mbar (20 °C)
Density :	approx. 1,2 g/cm3 (20 °C) Method : DIN 51757
Bulk density :	not determined
Vapour density in relation to air :	Not applicable
Solubility in water :	(20 °C) miscible
Soluble in ... :	fat not determined

pH value :	5 - 7 (20 °C, 100 g/l) Method : DIN 19268
Octanol/water partition coefficient (log Pow) :	< -1
Viscosity (dynamic) :	24 - 29 mPa.s (20 °C) Method : DIN 53019 50 % aqueous solution
Viscosity (kinematic) :	22 - 27 mm2/s (20 °C) Method : DIN 51562 50 % aqueous solution
Combustion number :	not determined

10. Stability and reactivity

Thermal decomposition : 360 °C
Source : Analogy

Hazardous reactions
No hazardous reactions when stored and handled according to prescribed instructions.

11. Toxicological information

Acute oral toxicity :	LD50 > 15.000 mg/kg (rat)
Acute inhalation toxicity :	not determined
Acute dermal toxicity :	not determined
Irritant effect on skin :	non-irritant (rabbit)
Irritant effect on eyes :	non-irritant (rabbit eye)
Sensitization :	non-sensitizing Source : literature
Mutagenicity :	Not mutagenic in Ames Test. Source : literature

Remarks
By analogy with a product of similar composition

12. Ecological information

Biodegradability :	> 80 % (28 d) good degradability Method : DIN 38412 T.24
Fish toxicity :	LC50 > 10 g/l (48 h, golden orfe) Method : DIN 38412 T.15

Clariant

Safety data sheet in accordance with 2001/58/EC
POLYGLYKOL 1000

Substance key: SXR024808
Version : 1 - 23 / EU

Revision Date: 31.10.2005
Date of printing : 27.08.2007

Bacteria toxicity : EC50 > 1.000 mg/l
Method : OECD 209

13. Disposal considerations

Product
In accordance with regulations for special waste, must be taken to an authorised special waste incineration plant.

14. Transport information

ADR	not restricted
ADNR	not restricted
RID	not restricted
IATA	not restricted
IMDG	not restricted

15. Regulatory information

Labelling in accordance with EC-Directives
The product does not require a hazard warning label in accordance with EC Directives

National regulations

Other regulations
Theshold limit value (German MAK-value) not determined.

16. Other information

Decimal notation: "Thousands" places are identified with a dot (example: 2.000 mg/kg means "two thousand mg/kg"). Decimal places are identified with a comma (example: 1,35 g/cm3).

The data are based on the current state of our knowledge, and are intended to describe the product with regard to the requirements of safety. The data should not be taken to imply any guarantee of a particular or general specification. It is the responsibility of the user of the product to ensure to his satisfaction that the product is suitable for the intended purpose and method of use. We do not accept responsibility for any harm caused by the use of this information. In all cases, our general conditions of sale apply.

Clariant

Safety Data Sheet in accordance with Regulation (EC) No 1907/2006

POLYGLYKOL 400

Substance key: SXR024804
Version : 3 - 3 / EU

Revision Date: 27.09.2007
Date of printing : 03.12.2008

1. Identification of the substance/preparation and of the company/undertaking

Trade name
POLYGLYKOL 400

Use of the substance/preparation.
Industry sector : Personal Care
Type of use : Techno-chemical industry.
Pharma

Identification of the company
Clariant Produkte (Deutschland) GmbH

65926 Frankfurt am Main
Telephone no. : +49 69 305 18000

Information about the substance/preparation
Div. Functional Chemicals/PRODUCT SAFETY
++49(0)69-305-2092/15315/32251
e-mail: FUN.EHS@clariant.com

Emergency telephone number : +49 69 305 6418

2. Hazards identification

No particular hazards known.

3. Composition/information on ingredients

Chemical characterization
polyethylene glycol, HO-(CH2-CH2O)n-H, average molecular mass 400

INCI name
PEG-8

CAS number : 25322-68-3

4. First aid measures

General information
Change soaked clothing

After inhalation
When inhaled remove to fresh air and seek medical aid.

After contact with skin
In case of contact with skin wash off with water.

After contact with eyes
In case of contact with eyes rinse thoroughly with water

After ingestion
No special measures necessary.

Clariant

Safety Data Sheet in accordance with Regulation (EC) No 1907/2006

POLYGLYKOL 400 Page 2

Substance key: SXR024804
Version : 3 - 3 / EU

Revision Date: 27.09.2007
Date of printing : 03.12.2008

5. Fire-fighting measures

Suitable extinguishing media
water spray jet
dry powder
foam
carbon dioxide

Special hazards from the substance itself, its combustion products or from its vapours
In case of fires, hazardous combustion gases are formed: Carbon monoxide (CO)

Special protective equipment for firefighting
Use self-contained breathing apparatus

6. Accidental release measures

Personal precautions
Wear suitable personal protective equipment.

Environmental precautions
Do not allow to enter drains or waterways

Methods for cleaning up/taking up
Pick up with absorbent material (eg sand, kieselgur, acid binder, universal binder, sawdust).
Flush away residues with water.

7. Handling and storage

Advice on safe handling
No special measures necessary if stored and handled as prescribed.

Further information on storage conditions
Keep container tightly closed and dry in a cool, well-ventilated place
Do not keep at temperatures above 30 °C.
Recommended storage temperature: 10 - 25 °C.

8. Exposure controls / personal protection

Occupational exposure controls

General protective measures
In line with Bulletin 38 Of DFG Senate Comm.(1/7/2002) polyethylene glycol (PEG mean mol. wt 200-600) has been assigned a max. work place concen. value of 1000mg/m3 with peak limit Category II (8)

Hygiene measures
Observe the usual precautions when handling chemicals.

Respiratory protection :	Use respiratory protection in case of insufficient exhaust ventilation or prolonged exposure Full mask to standard DIN EN 136 Filter A (organic gases and vapours) to standard DIN EN 141 The use of filter apparatus presupposes that the environment atmosphere contains at least 17% oxygen by volume, and does not exceed the maximum gas concentration, usually 0.5% by volume. Relevant guidelines to be considered include EN 136/141/143/371/372 as well as other national regulations.
Hand protection :	For long-term exposure: Butyl rubber gloves. Minimum breakthrough time / gloves : 480 min Minimum thickness / gloves 0,7 mm For short-term exposure (splash protection): Nitrile rubber gloves. Minimum breakthrough time / gloves : 30 min Minimum thickness / gloves 0,4 mm These types of protective gloves are offered by various manufacturers. Please note the manufacturers' detailed statements, especially about the minimum thickness and the minimum breakthrough time. Consider also the particular working conditions under which the gloves are being used.
Eye protection :	safety glasses

9. Physical and chemical properties

Form :	Liquid
Colour :	colourless
Odour :	odourless
Freezing point :	4 - 8 °C Method : European Pharmacopoeia / 2.2.18
Pourpoint :	approx. 6 °C Method : ASTM D 97
Boiling point :	> 200 °C
Flash point :	240 °C Method : DIN 51376 (open cup)
Ignition temperature :	360 °C Method : DIN 51794
Oxidizing properties :	Not applicable
Self-ignition temperature :	Not applicable
Flammability	

Lower explosion limit :	Not applicable
Upper explosion limit :	Not applicable
Combustion number :	Not applicable
Evaporation rate :	not tested.
Vapour pressure :	< 0,1 mbar (20 °C)
Density :	approx. 1,126 g/cm3 (20 °C) Method : DIN 51757
Bulk density :	Not applicable
Vapour density in relation to air :	not tested.
Solubility in water :	(20 °C) miscible
Soluble in ... :	fat not tested.
pH value :	5 - 7 (20 °C, 100 g/l) Method : DIN 19261
Octanol/water partition coefficient (log Pow) :	Not applicable
Viscosity (kinematic) :	ca. 97 - 110 mm2/s (20 °C) Method : DIN 51562

10. Stability and reactivity

Thermal decomposition :	360 °C Source : Analogy

Hazardous reactions
No hazardous reactions when stored and handled according to prescribed instructions.

11. Toxicological information

Acute oral toxicity :	LD50 > 15.000 mg/kg (rat)
Acute inhalation toxicity :	not tested.
Acute dermal toxicity :	not tested.
Irritant effect on skin :	non-irritant (rabbit)
Irritant effect on eyes :	non-irritant (rabbit eye)
Sensitization :	non-sensitizing Source : literature

Mutagenicity : Not mutagenic in Ames Test.

Remarks
By analogy with a product of similar composition

12. Ecological information

Biodegradability :	> 80 % (28 d) readily degradable Method : OECD 301 E
Fish toxicity :	LC50 > 10 g/l (48 h, golden orfe) Method : DIN 38412 T.15
Bacteria toxicity :	EC0 > 12,5 g/l (3 h) Method : OECD 209
Dissolved Organic carbon (DOC) :	492 mg/g
Chemical oxygen demand (COD) :	1.858 mg/g Method : DIN 38409-H41

13. Disposal considerations

Product
In accordance with regulations for special waste, must be taken to an authorised special waste incineration plant.

14. Transport information

ADR	not restricted
ADNR	not restricted
RID	not restricted
IATA	not restricted
IMDG	not restricted

15. Regulatory information

Labelling in accordance with EC-Directives
The product does not require a hazard warning label in accordance with EC Directives

Chemical Safety Assessment
No Chemical Safety Assessment (CSA) is yet available for the substance, or for the ingredients of the preparation, which constituta(s) this product.

16. Other information

Decimal notation: "Thousands" places are identified with a dot (example: 2.000 mg/kg means "two thousand mg/kg"). Decimal places are identified with a comma (example: 1,35 g/cm3).

The data are based on the current state of our knowledge, and are intended to describe the product with regard to the requirements of safety. The data should not be taken to imply any guarantee of a particular or general specification. It is the responsibility of the user of the product to ensure to his satisfaction that the product is suitable for the intended purpose and method of use. We do not accept responsibility for any harm caused by the use of this information. In all cases, our general conditions of sale apply.

ISP

SAFETY DATA SHEET (1907/2006)

72338I

Revision Date: 02/02/2011
Issuing Date: 02/02/2011

PVP IODINE

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Identification of the substance or preparation

Product Code:	72338I
Product Name:	PVP IODINE
CAS-No:	25655-41-8
Company/Undertaking Identification:	International Specialty Products 1361 Alps Rd. Wayne, NJ 07470, U.S.A. Telephone: (973) 628-4000 Distributed By: ISP (Great Britain) Co. Ltd. Waterfield, Tadworth Surrey KT20 5HQ, United Kingdom Tel: +44 1737 377 000
E-mail Address:	MSDS@ISPCORP.COM
Emergency Telephone:	+32.3.575.55.55 (SGS)
Prepared By:	Product Stewardship
Product Use Description:	Pharmaceutical

2. HAZARDS IDENTIFICATION

EU Classification: This substance is not classified as dangerous according to European Union legislation

Hazard Summary

Target Organs:	• Eyes • Skin • Respiratory System
Primary Routes of Entry:	Eyes. Skin. Ingestion. Inhalation.
Acute Health Hazard:	Mild skin irritant May cause respiratory tract irritation.
Chronic Health Hazard:	None known

Symptoms of Overexposure

Eye Contact:	Not hazardous
Skin contact:	Mild skin irritant
Ingestion:	Not hazardous
Inhalation:	May cause respiratory tract irritation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components:	Weight %	Directive 67/548/EEC	REACH Classification 2006/1907/EC	ECC Number
2-Pyrrolidinone, 1-ethenyl-, homopolymer, compound with Iodine	100	NA	N/A	NA

4. FIRST AID MEASURES

Eye Contact: Flush with plenty of water.

Skin Contact: Wash off with soap and water. Get medical attention if irritation develops and persists

Ingestion: Do not induce vomiting. If conscious, give 2 glasses of water. Get immediate medical attention.

Inhalation: If inhaled, remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Get medical attention.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: All types

Combustion/Explosion Hazards: May form explosive dust-air mixture.

Special Protective Equipment For Fire-Fighters: Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear suitable protective equipment.

Environmental Precautions: None known.

Methods for Cleaning Up: Clean up promptly by scoop or vacuum. Avoid dust formation. Avoid dust accumulation in enclosed space.

7. HANDLING AND STORAGE

Handling: Avoid dust formation. Avoid dust accumulation in enclosed space. Avoid breathing dust. Wash thoroughly after handling.

Storage: Keep container tightly closed. Keep in a dry, cool place. Keep away from direct sunlight.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Measures: Use only in well-ventilated areas.

Respiratory Protection: Use with adequate ventilation. Wear respiratory protection

Hand Protection: Wear protective gloves.

Eye Protection: Safety glasses.

Environmental Controls: Not determined.

Exposure Limits:

Components:	German Recommended Exposure Limits (MAK):	UK Workplace Exposure Limits (WELs):	Belgium - Recommended Exposure Limits:	Italy - Recommended Exposure Limits:	France - Recommended Exposure Limits:
2-Pyrrolidinone, 1-ethenyl-, homopolymer, compound with iodine (100)	Not determined	Not determined	3mg/m³TWA 10mg/m³TWA	Not Determined	Not Determined

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder

Color: Reddish brown

pH: Not determined

Bulk Density: 0.55 g/cm3

Boiling Point (°F): Not determined

Melting/Freezing Point (°F): Not determined

Vapor Pressure: Not determined

Solubility: Miscible in water

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions.

Conditions to Avoid: Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid dust formation. Avoid dust accumulation in enclosed space.

Materials to Avoid: Strong oxidizing agents, Reducing agents

Hazardous decomposition products: nitrogen oxides (NOx), Iodine

11. TOXICOLOGICAL INFORMATION

Toxicity Test:

Acute Oral Toxicity (LD50):	6800 mg/kg (Rat)
Acute Dermal Toxicity (LD50):	Not Determined
Acute Inhalation Toxicity (LC50):	Not Determined
Eye Irritation:	Non-irritating to rabbit eye. (10% aqueous solution)
Skin Irritation:	Non-irritating to rabbit skin (10% solution) Non irritating (Human RIPT 10% solution) Mild skin irritation (Rabbit)
Sensitization:	5,900 patients over 3 years= 0.03% incidence of sensitization (Humans).
Mutagenicity:	Non-mutagenic. (L5178Y Mouse (TK+/-) Lymphoma Assay)
Carcinogenicity:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
Other Information	Subchronic Oral Toxicity: 90 day Rat 0-3 mg/kg/week (10% solution) No significant adverse reactions.

12. ECOLOGICAL INFORMATION

Persistence and Degradability:	Not determined.
Ecotoxicity:	Not determined
Bioaccumulative Potential:	Not determined
Mobility:	Not determined

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods:	Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

Land Transport:

DOT (Non-Bulk):

Not regulated DOT

DOT (Bulk):

Air Transport (IATA):

Not regulated IATA

Sea Transport (IMO):

Not regulated IMDG

ADR:

Not regulated ADR

15. REGULATORY INFORMATION

Classification: This substance is not classified as dangerous according to European Union legislation

Inventories	Status
TSCA	Listed
DSL	Listed
NDSL	Not Listed
ENCS	Listed
AICS	Listed
EINECS	Not Listed
ELINCS	Not Listed
NZIoC	Listed
KECI	Listed
PICCS	Listed
IECSC	Listed

California Proposition 65 Carcinogens & Reproductive Toxicity (CRT) List: This product does not contain any chemicals known to State of California to cause cancer, birth, or any other reproductive defects.

Germany VCI Assigned Classification into Water Endangering Classes (WGK) List: Not determined

16. OTHER INFORMATION

Prepared By: Product Stewardship

Revision Date: 02/02/2011

MSDS sections updated: This data sheet contains changes from the previous version in section(s) 1,2,4,5,8

Legend: N.Av.= Not Available; N.A.= Not Applicable

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End of Safety Data Sheet

Document : Material Safety Data Sheet (MSDS)
Product : Primojel®
Product code : 44000
Issue date : 15 January 2008
Edition No. : 2

Material Safety Data Sheet
According to EC Directive 91/555/EEC

This document should be read in conjunction with the Ingredient Declaration and the Certificate of Standards for the relevant product or product category.

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product
Sodium Starch Glycolate, Product name: Primojel®

Manufacturer
DMV-Fonterra Excipients B.V., AVEBE-weg 1, 9607 PT Foxhol, Netherlands

Supplier identification
DMV-Fonterra Excipients GmbH & Co. KG, Klever Strasse 187, 47574 Goch, Germany

Emergency telephone No: +31 (0)413 372222, ask for the Safety Department

2. Composition/information on ingredients

Composition
See Ingredient Declaration

Synonyms
Carboxymethylether, sodium salt of potato starch

CAS-No. : 9063-38-1
EINECS-NO. : n.a.

3. Hazards identification

No hazardous product as specified in Directive 67/548/EEC.

4. First aid measures

After inhalation: fresh air
After skin contact: wash off with plenty of water. After eye contact: rinse out with water.
After swallowing (large amounts): get medical attention.

DMV-Fonterra Excipients GmbH & Co. KG
Klever Strasse 187, P.O. Box 20 21 20
47568 Goch - Germany
Tel. +49 (0)2823 9288 770
Fax. +49 (0)2823 9288 7799
www.dmv-fonterra-excipients.com

Document : Material Safety Data Sheet (MSDS)
Product : Primojel®
Product code : 44000
Issue date : 15 January 2008
Edition No. : 2

5. Hazards Fire-fighting measures

Suitable extinguishing media:
In adaptation to materials stored in the immediate neighbourhood.

Special risks:
Combustible

6. Hazards Accidental release measures

Person-related precautionary measures:
Avoid generation of dusts; do not inhale dusts

Procedures for cleaning / absorption:
Take up dry. Forward for disposal. Clean up affected area. Avoid generation of dusts

7. Handling and storage

Handling:
Store protected from solvents.

Storage:
Tightly closed. Dry. At + 5°C to +25°C.

8. Exposure controls/personal protection
Personal protective equipment:

Respiratory protection: Required when dusts are generated

Eye protection: Required

Hand protection: Use recommended

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Industrial hygiene:
Wash hands after working with substance

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Document : Material Safety Data Sheet (MSDS)
Product : Primojel®
Product code : 44000
Issue date : 15 January 2008
Edition No. : 2

9. Physical and chemical properties

For chemical and physico-chemical data see the Certificate of Standards

For information concerning explosion data, consult our safety department tel. +31 413 372222

10. Stability and reactivity

Conditions to be avoided
No information available

Substances to be avoided
No information available

Hazardous decomposition products
No information available

11. Toxicological information

Acute toxicity
Quantitative data on the toxicity of this product are not available

Further toxicological information
No toxic effects are to be expected when the product is handled appropriately.

Further data
The product should be handled with the care usual when dealing with chemicals.

12. Ecological information

Ecotoxic effects:
Quantitative data on the ecological effect of this product are not available.

Further ecologic data:
No ecological problems are to be expected when the product is handled and used with due care and attention.

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Document : Material Safety Data Sheet (MSDS)
Product : Primojel®
Product code : 44000
Issue date : 15 January 2008
Edition No. : 2

13. Disposal considerations

Products
There are no uniform EC Regulations for the disposal of chemicals or residues. Chemical residues
generally count as special waste. The disposal of the latter is regulated in the EC member countries
through corresponding laws and regulations. We recommend that you contact either the authori-
ties in charge or approved waste disposal companies which will advise you on how to dispose of
special waste.

Packaging
Disposal in compliance with official regulations. Handle contaminated packaging in the same way as the substance itself. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

14. Transport information

Not subject to transport regulations.
This product can be declared as “starch“.

15. Regulatory information

Labelling according to EC directives

Symbol: None
R-phrases: None
S-phrases: S16; Keep away from sources of ignition - No smoking

16. Other information

In case of any questions the experts in the Safety Department of DMV International should be consulted. Telephone No.: +31 413 372222

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Document : Material Safety Data Sheet (MSDS)
Product : Primojel®
Product code : 44000
Issue date : 15 January 2008
Edition No. : 2

Name : Armand M. Janssen
Job title : Manager Regulatory Affairs
Signature :

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www.dmv-fonterra-excipients.com

BASF
The Chemical Company

Safety data sheet

BASF Safety data sheet according to 91/155/EEC
Date / Revised: 14.09.2004 Version: 7.0
Product: 1,2-Propylene Glycol pharma
(30055286/SDS_COS_EU/EN)
Date of print 11.10.2007

1. Substance/preparation and company identification

1,2-Propylene Glycol pharma

Use: pharmaceutical adjuvant

Company:
BASF Aktiengesellschaft
67056 Ludwigshafen
GERMANY
Operating Division Petrochemicals
Telephone: +49 621 60-46050
Telefax number: +49 621 60-6646050
E-mail address: product_safety-alkylene_oxides_and_glycols@basf.com

Emergency information:
Telephone: +49 180 2273-112
Telefax number: +49 621 60-92664

2. Composition/information on ingredients

Chemical nature

INCI Name: Propylene Glycol

propane-1,2-diol
CAS Number: 57-55-6
EC-Number: 200-338-0

3. Hazard identification

No particular hazards known.

4. First-aid measures

General advice:
Remove contaminated clothing.

On skin contact:
Wash thoroughly with soap and water.

On contact with eyes:
Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:
Rinse mouth and then drink plenty of water.

Note to physician:
Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

5. Fire-fighting measures

Suitable extinguishing media:
carbon dioxide, dry extinguishing media, water spray, alcohol-resistant foam

Special protective equipment:
Wear a self-contained breathing apparatus.

Further information:
Contaminated extinguishing water must be disposed of in accordance with official regulations.

6. Accidental release measures

Personal precautions:
Handle in accordance with good industrial hygiene and safety practice.

Environmental precautions:
Do not empty into drains.

Methods for cleaning up or taking up:
For large amounts: Pump off product.
For residues: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr). Dispose of absorbed material in accordance with regulations.

7. Handling and storage

Handling

Ensure thorough ventilation of stores and work areas.

Protection against fire and explosion:
Take precautionary measures against static discharges.

Storage

Suitable materials for containers: aluminum, Stainless steel 1.4439, High density polyethylene (HDPE), light-impervious
Unsuitable materials for containers: zinc
Further information on storage conditions: Keep container tightly closed and dry; store in a cool place. Protect from air. Protect from atmospheric humidity. Protect contents from the effects of light.

Storage stability:
Storage temperature: < 40 °C
The stated storage temperature should be noted.
Storage duration: 12 Months

8. Exposure controls and personal protection

Personal protective equipment

Hand protection:
Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact
(Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), polyvinylchloride (0.7 mm) and other
Manufacturer's directions for use should be observed because of great diversity of types.
Supplementary note: The specifications are based on own tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined in accordance with EN 374.

Eye protection:
Safety glasses with side-shields (frame goggles) (EN 166)

Body protection:
light protective clothing

General safety and hygiene measures:
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Form:	liquid
Colour:	colourless
Odour:	almost odourless
Melting point:	-60 °C

Boiling range:	186 - 190 °C (1,013 mbar)	
Flash point:	103 °C	(DIN 51758)
Lower explosion limit:	2.6 %(V)	
Upper explosion limit:	12.6 %(V)	
Ignition temperature:	410 °C	(DIN 51794)
Vapour pressure:	0.186 mbar (20 °C) 1.75 mbar (50 °C)	
Density:	1.036 g/cm3 (20 °C)	(DIN 51757)
Solubility in water:	fully soluble (20 °C)	
Solubility (qualitative) solvent(s):	polar solvents soluble	
Partitioning coefficient n-octanol/water (log Pow):	-0.92	
Viscosity, dynamic:	60.5 mPa.s (20 °C)	

10. Stability and reactivity

Conditions to avoid:
> 40 °C
Avoid humidity. Avoid daylight. Disregard of the conditions mentioned may result in undesirable decomposition reactions.

Substances to avoid:
zinc, strong oxidizing agents

Hazardous reactions:
No hazardous reactions if stored and handled as prescribed/indicated.

Possible decomposition products:
carbonyl compounds, Dioxolan derivatives

11. Toxicological information

LD50/oral/rat: > 2,000 mg/kg

by inhalation/rat:
Inhalation-risk test (IRT): No mortality within 8 hours as shown in animal studies. The inhalation of a highly saturated vapor-air mixture represents no acute hazard.

LD50/dermal/rabbit: > 5,000 mg/kg

Primary skin irritation/rabbit: non-irritant (Draize test)

Primary irritations of the mucous membrane/rabbit: non-irritant (OECD Guideline 405)
Literature data.

Sensitization/Guinea pig maximization test:
no sensitizing effect

12. Ecological information

Ecotoxicity

Toxicity to fish:
Oncorhynchus mykiss/LC50 (96 h): > 100 mg/l

Aquatic invertebrates:
OPP 72-2 (EPA-guideline)
Daphnia magna/EC50 (48 h): > 100 mg/l
Literature data.

Aquatic plants:
EC50 (72 h): > 100 mg/l
Literature data.

Microorganisms/Effect on activated sludge:
DEV-L2
> 5,000 mg/l
Inhibition of degradation activity in activated sludge is not to be anticipated during correct introduction of low concentrations.

Persistence and degradability

Elimination information

Test method:	OECD 301 A (new version)
Method of analysis:	DOC reduction
Degree of elimination:	> 70 % (28 d)
Evaluation:	Readily biodegradable.

Chemical oxygen demand (COD): 1,585 mg/g

Bioaccumulation potential

Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is not to be expected.

Additional information

Other ecotoxicological advice:
Do not release untreated into natural waters.

13. Disposal considerations

Must be dumped or incinerated in accordance with local regulations.

Contaminated packaging:
Uncontaminated packaging can be re-used.
Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14. Transport information

Not classified as hazardous under transport regulations (ADR RID ADNR IMDG/GGV/See ICAO/IATA)

15. Regulatory information

Regulations of the European union (Labelling) / National legislation/Regulations

EC-Number: 200-338-0

Not subject to labelling in accordance with EEC Directives.

Other regulations

16. Other information

Vertical lines in the left hand margin indicate an amendment from the previous version.

The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. Recipients of our product must take responsibility for observing existing laws and regulations.

VANI PHARMA Labs Limited

MATERIAL SAFETY DATA SHEET (MSDS)
As per Commission Regulation (EU) No 453 / 2010
PRODUCT – PROPYPHENAZONE Ph.Eur.

Date of compilation	24.12.2010

SECTION 1: Identification of the Substance / Mixture and of the Company / Undertaking		
1.1	**Product identifier:**	
	General name	: PROPYPHENAZONE
	Other Non proprietary names	: Iso propyl antipyrine
	Chemical name	: 1,2-Dihydro-1,5-Dimethyl-4-(1-Methyl)-2-Phenyl-3H-: Pyrazol-3-one. : 4- Isopropyl-2,3 Dimethyl –1-Phenyl-3-Pyrazolin-5-one.
	Cas registry no.	: 479-92-5
	Molecular formula	: $C_{14}H_{18}N_2O$
	Molecular weight	: 230.3
1.2	**Relevant identified uses of the substance or mixture and uses advised against** Active pharmaceutical ingredient (Analgesic , Antipyretic)	
1.3	**Details of the supplier of the safety data sheet** M/s.Vani Pharma Labs Limited Plot No.11& 12, I.D.A., Jeedimetla, Hyderabad- 500 055, A.P, INDIA.	
1.4	**Emergency telephone number** 91-40-23096262	
SECTION 2: Hazards Identification		
2.1	**Classification of the substance or mixture** **According to EC-classification** **(EC No.:207-539-2)** R phrases Hazard symbols (Xn) H302	 R22 Harmful if swallowed Harmful Harmful if swallowed
2.2	**Label elements** **Labelling according to Regulation (EC)** **Hazard pictograms**   Hazard statements H302 Harmful if swallowed R 22 Harmful if swallowed Xn : Harmful	
2.3	**Other hazards** Not known	

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VANI PHARMA Labs Limited

MATERIAL SAFETY DATA SHEET (MSDS)
As per Commission Regulation (EU) No 453 / 2010
PRODUCT – PROPYPHENAZONE Ph.Eur.

SECTION 3: Composition / Information on Ingredients		
Chemical characterization General name : PROPYPHENAZONE Chemical name: 1,2-Dihydro-1,5-Dimethyl-4-(1-Methyl)-2-Phenyl-3H-Pyrazol-3-one. 4- Isoporopyl-2,3 Dimethyl –1-Phenyl-3-Pyrazolin-5-one. Cas registry No.: 479-92-5 Molecular Formula: $C_{14}H_{18}N_2O$ Molecular Weight : 230.3		
3.1	**Substances**	
	Normal Adult Dose	No information available
	Average Effects	
	Overdose effect	
	Hazards	
	First Aid	
	After inhalation	Remove to fresh air. Seek medical treatment immediately.
	After contact with skin	In case of contact with skin wash off immediately with soap and water.
	After contact with Eyes:	In case of contact with eyes rinse thoroughly with water.
	After ingestion:	Induce vomiting if patient is conscious, seek medical advice.
3.2	**Mixtures:**	No information available
SECTION 4: First Aid Measures		
4.1	**Description of first aid measures**	
	After inhalation	Remove to fresh air. Seek medical treatment immediately.
	After contact with skin	In case of contact with skin wash off immediately with soap and water.
	After contact with Eyes	In case of contact with eyes rinse thoroughly with water.
	After ingestion	Induce vomiting if patient is conscious, seek medical advice
4.2	**Most important symptoms and effects, both acute and delayed**	
	No information available	
4.3	**Indication of any immediate medical attention and special treatment needed**	
	No information available	
SECTION 5: Firefighting Measures		
5.1	**Extinguishing media**	
	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.	
5.2	**Special hazards arising from the substance or mixture**	
	Conditions to avoid	Avoid contact with heat. Risk of dust explosion.
	Incompatibilities	Incompatible with oxidizing agents
	Decomposition Products	CO_x, NO_x and other noxious gases or vapours in case of incomplete combustion.

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MATERIAL SAFETY DATA SHEET (MSDS)
As per Commission Regulation (EU) No 453 / 2010
PRODUCT – PROPYPHENAZONE Ph.Eur.

5.3	**Advice for firefighters**	
	Fire and Explosion Hazards	Emits toxic fumes under fire condition.
	Fire fighting procedure	As with all fires, evacuate personnel to a safe area. Firefighters should use self – contained breathing equipment and protective clothing.
	Further information	Collect contaminated fire extinguishing water Separately. This must not be discharged into drains. Fire residues and fire extinguishing water must be disposed off in a proper manner.
SECTION 6: Accidental Release Measures		
6.1	**Personal precautions, protective equipment and emergency procedures**	
	General	Switch off electrical equipment and any of other sources of ignition
6.2	**Environmental precautions**	
	Spills / Leaks	Vacuum or sweep up materials and place into a suitable disposal container
6.3	**Methods and material for containment and cleaning up**	
	Pick up residues manually and wipe with a small quantity of detergent and place into a suitable disposal container. When picked up, send to waste disposal site or incineration plant. Avoid raising dust. Provide exhaust ventilation if dust is formed	
6.4	**Reference to other sections**	
	Not applicable	
SECTION 7: Handling and Storage		
7.1	**Precautions for safe handling**	
	Handling	Avoid inhalation. Avoid prolonged exposure. Avoid contact with eyes, skin and clothing.
7.2	**Conditions for safe storage, including and incompatibilities**	
	Storage	Store in a well closed container, protect from light. Keep away from chemicals.
7.3	**Specific end use(s)**	
		Apart from the uses in section 1.2 no other specifics uses are not known
SECTION 8: Exposure Controls / Personal Protection		
8.1	**Control parameters**	
	No information available	
8.2	**Exposure controls**	
	Engineering Controls	Use adequate ventilation to keep airborne concentrations low personal protective equipment.
	Eyes	Wear appropriate protective eyeglasses or chemical safety goggles.
	Skin	Wear appropriate protective gloves, suite to prevent skin exposure
	Clothing	Wear appropriate protective clothing to prevent skin exposure.
	Respirators	Use appropriate protective mask.

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VIANI PHARMA Labs Limited

MATERIAL SAFETY DATA SHEET (MSDS)
As per Commission Regulation (EU) No 453 / 2010
PRODUCT – PROPYPHENAZONE Ph.Eur.

SECTION 9: Physical and Chemical Properties		
9.1	**Information on basic physical and chemical properties**	
	Appearance	White or slightly yellowish Crystalline Powder
	Odour	odourless
	Melting Point	102 to 106°C.
	Solubility in Water	Slightly soluble in water, Freely soluble in alcohol
	Boiling Point	No information available
	Specific Gravity	No information available
	Vapor Density	No information available
	Vapor Pressure	No information available
	Evaporation Rate	No information available
9.2	**Other information**	
	No information available	
SECTION 10: Stability and Reactivity		
10.1	**Reactivity**	
		Under specified storage conditions the material does not have any adverse reactivity.
10.2	**Chemical stability**	
		Stable under normal storage conditions
10.3	**Possibility of hazardous reactions**	
		Emits toxic fumes under fire condition.
10.4	**Conditions to avoid**	
		Heat
10.5	**Incompatible material**	
	Incompatibility	Strong Oxidizing agents
10.6	**Hazardous decomposition products**	
	Decomposition Products	CO_x, NO_x and other noxious gases or vapours incase of incomplete combustion.
SECTION 11: Toxicology Information		
11.1	**Information on toxicological effects**	
	Acute Oral toxicity	LD50 (oral-rat) 860 mg/Kg
	Irritancy	
	Skin Contact	Health injuries are not known or expected under normal use
	Eye Contact	Irritation possible
	Ingestion	Health injuries are not known or expected under normal use
	Inhalation	Poor chance of inhalation
	Target organs	No information available
	Carcinogenicity	No information available
	Mutagenicity	No information available
	Biodegradability	No information available

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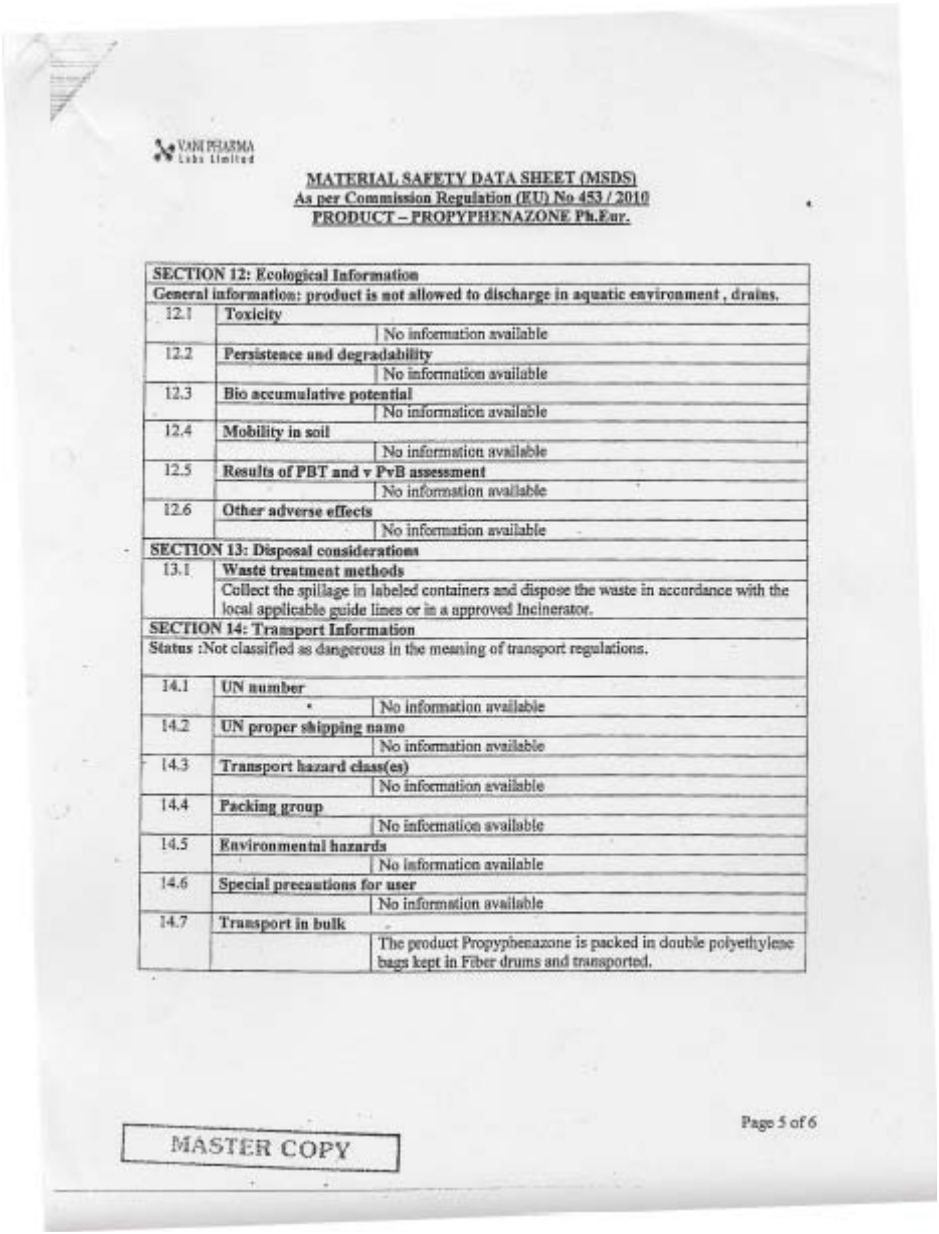

VANI PHARMA Labs Limited

MATERIAL SAFETY DATA SHEET (MSDS)
As per Commission Regulation (EU) No 453 / 2010
PRODUCT – PROPYPHENAZONE Ph.Eur.

SECTION 12: Ecological Information		
General information: product is not allowed to discharge in aquatic environment , drains.		
12.1	**Toxicity**	
		No information available
12.2	**Persistence and degradability**	
		No information available
12.3	**Bio accumulative potential**	
		No information available
12.4	**Mobility in soil**	
		No information available
12.5	**Results of PBT and v PvB assessment**	
		No information available
12.6	**Other adverse effects**	
		No information available
SECTION 13: Disposal considerations		
13.1	**Waste treatment methods**	
	Collect the spillage in labeled containers and dispose the waste in accordance with the local applicable guide lines or in a approved Incinerator.	
SECTION 14: Transport Information		
Status :Not classified as dangerous in the meaning of transport regulations.		
14.1	**UN number**	
		No information available
14.2	**UN proper shipping name**	
		No information available
14.3	**Transport hazard class(es)**	
		No information available
14.4	**Packing group**	
		No information available
14.5	**Environmental hazards**	
		No information available
14.6	**Special precautions for user**	
		No information available
14.7	**Transport in bulk**	
		The product Propyphenazone is packed in double polyethylene bags kept in Fiber drums and transported.

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VANI PHARMA Labs Limited

MATERIAL SAFETY DATA SHEET (MSDS)
As per Commission Regulation (EU) No 453 / 2010
PRODUCT – PROPYPHENAZONE Ph.Eur.

SECTION 15: Regulatory Information		
15.1	**Safety, health and environmental regulations / legislation specific for the substance or mixture**	
	S 24/25	Avoid contact with skin and eyes
	S 36/37/39	Wear suitable clothing / gloves / eye/face protection
	R22	Harmful if swallowed
	Hazard symbol (Xn)	Harmful
	H302	Harmful if swallowed
15.2	**Chemical safety assessment**	
	No information available	
SECTION 16: Other Information		
	Full text of H- statements ,S & R phrases referred to under sections 2 & 15	
	H302	Harmful if swallowed
	Hazard symbol (Xn)	Harmful
	S 24/25	Avoid contact with skin and eyes
	S 36/37/39	Wear suitable clothing / gloves / eye/face protection
	R22	Harmful if swallowed
	Status: The information presented in this MSDS is collected from published sources and believed to be true and correct. However the accuracy and completeness of this information and any recommendation or suggestion made are without any warranty or guarantee. It is the responsibility of the user to check the correctness and act accordingly for making use of the material.	

Document No.: MSDS/E&S/PP/01		**Rev. No.: 00**
Prepared by	Checked by	Approved by
G. Bhemeshwara Rao	M.K. Nagi Reddy	M.Suhasini

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Safety data for sucrose

General

Synonyms: sugar, cane sugar, saccharose, beta-d-fructofuranosyl-alpha-d-glucopyranoside, beta-d-fructofuranoside, beet sugar, confectioner's sugar, granulated sugar, NCI-C56597, icing sugar, rock candy, saccharum
Use: natural sweetner
Molecular formula: $C_{12}H_{22}O_{11}$
CAS No: 57-50-1
EC No: 200-334-9

Physical data

Appearance: white crystals or powder
Melting point: 160 -180 C (decomposes)
Boiling point:
Vapour density:
Vapour pressure:
Density (g cm^{-3}): 1.59
Flash point:
Explosion limits:
Autoignition temperature:
Water solubility: substantial
Refractive index: 1.5376

Stability

Stable. Combustible. Incompatible with strong oxidizing agents. Hydrolyzed by dilute acids and by invertase.

Toxicology

Inhalation of powder may cause respiratory irritation.

Toxicity data

(The meaning of any abbreviations which appear in this section is given)
ORL-RAT LD50 29700 mg kg^{-1}
IPR-MUS LD50 14000 mg kg^{-1}

Transport information

Non-hazardous for air, sea and road freight.

Personal protection

Thought to present no health hazard.

Sigurnosna lista

Prema Regulaciji (EC) br.1907/2006 (REACH)

Datum izdavanja: 11.08.2008
Zamjensko izdanje: 30.07.2006

1. Identifikacija tvari/pripravka i tvornice/poduzec´a

Identifikacija produkta

Kataloški broj: 102975

Ime produkta: Sorbitol FP tekuc´i (sorbitol sirup, nekristalizirani) EMPROVE® Ph Eur,BP,E 420

Uporaba tvari/preparata

Farmaceutska proizvodnja i analiza

Identifikacija tvornice/poduzec´a

Tvornica: Merck KGaA * 64271 Darmstadt * Njemacka * Phone: +49 6151 72-0

Broj hitnog telefona: Tel.: 01 4843 646/647/745

Za informacije kontaktirati: EHSQ/EHS-PI * e-mail: prodsafe@merck.de

2. Opisi štetnosti:

Nije štetan produkt kao što je navedeno u direktivi 67/548/EEC.

3. Sastav/informacije o sastojcima

Vodena otopina. Preparat sadrz˘i: sorbitol.

4. Mjere prve pomoc´i:

Nakon udisanja: svezi zrak. Nakon dodira s kozom:oprati s mnogo vode.Odmah ukloniti kontaminiranu odecu.Nakon dodira s ocima: sirom otvorenih kapaka isprati oci velikom kolicinom vode. Nakon gutanja: dati osobi piti vode (dvije case najvise). Ako se osoba osjeca lose posavjetovati se s doktorom.

5. Mjere protiv poz˘ara:

Pogodne tvari za gašenje poz˘ara: Voda, ugljik-dioksid, pjena, prah.

Posebne opasnosti: Pripravljeno sa zapaljivim sastojcima.

Posebna zaštitna oprema za gašenje poz˘ara: ˘ju bez aparata za disanje.

6. Mjere za sprecavanje nesreca:

Osobne mjere zaštite: Ne udisati pare/aerosole.

Mjere za zaštitu okoliša: Pokupiti s materijalom koji apsorbira tekuc´ine (npr. Chemizorb®).
Zbrinuti na odgovarajuci nacin za kemiski otpad. Pocistiti zahvacenu povrsinu..

Merckova sigurnosna lista

Prema Regulaciji (EC) br.1907/2006 (REACH)

Kataloški broj: 102975
Ime produkta: Sorbitol FP tekuc´i (sorbitol sirup, nekristalizirani) EMPROVE® Ph Eur,BP,E420

7. Rukovanje i skladištenje

Rukovanje: Nema daljnjih zahtjeva.
Skladištenje: Dobro zatvoreno. Na +5˚C do +30˚C.

8. Kontrola izlaganja/osobna zaštita

Osobna zaštitna oprema:
Zastitna odjeca mora se odabrati cpecificno za svako radno mesto, ovisno o koncentracijama i kolicini opasnih tvari kojima se rukuje. Otpornost zastitne odjecena kemikalija treba se doznati od dobavljaca.

Zaštita dišnih organa:	potrebno ako nastaju pare/aerosoli	
Zaštita oc˘iju:	zahtijeva	
Zaštita ruku:	U potpunom dodiru:	
	Materijal za rukavice:	nitrilna guma
	Debljina slojeva:	0.11mm
	Vrijeme prodiranja:	> 480 Min
	U dodiru s kapljicama:	
	Materijal za rukavice:	nitrilna guma
	Debljina slojeva:	0.11mm
	Vrijeme prodiranja:	> 480 Min.

Zaštitne rukavice za upotrebu trebaju biti u skladu s odredbama EC smjernicama 89/686/EEC i standardima EN374, npr. KCL 741 Dermatril® L (puni kontakt), 741 Dermatril® L (kontakt prskanjem). Vrijeme prodiranja navedeno gore odredeno je u KCL laboratorijskim testiranjima prema EN374 s uzorcima preporuc˘enim tipova rukavica.
Te preporuke se odnose samo na produkte navedene u sigurnosnim listama i nabavljene kod nas i u svrhu koja je kod nas navedena. Kad se otapa ili miješa s drugim supstancama ili pod uvjetima koji odstupaju od navedenih u EN374, molimo kontaktirati proizvodac˘a CE-odobrenih rukavica (npr. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Industrijska higijena: Promijeniti kontaminiranu odjec´u. Oprati ruke nakon rada sa supstancom.

9. Fizic˘ka i kemijska svojstva:

Oblik:	viskozno	
Boja:	bezbojno	
Miris:	bez mirisa	
pH vrijednost	(20 ˚C) ~ 6	(50% otopina)
Viskozitet dinamic˘ki	(20 ˚C) ~ 210 mPa*s	
Toc˘ka tališta	nije dostupan	
Toc˘ka vrelišta	nije dostupan	
Temperatura zapaljenja	nije dostupan	
Plamište	nije dostupan	
Granice eksplozije	donja- nije dostupan	gornja- nije dostupan
Gustoc´a	~ 1.3 g/cm3	
Topljivost u vodi	topljiv	

Merckova sigurnosna lista

Prema Regulaciji (EC) br.1907/2006 (REACH)

Kataloški broj: 102975
Ime produkta: Sorbitol FP tekuc´i (sorbitol sirup, nekristalizirani) EMPROVE® Ph Eur,BP,E420

10. Stabilnost i reaktivnost

Uvjeti koji se trebaju izbjec´i : Jako zagrijavanje.
Tvari koje treba izbjegavati : nema dostupnih informacija
Štetni produkti raspadanja: nema dostupnih informacija

11. Toksikološke informacije

Akutna toksic˘nost: Kvantitativni podaci o toksic˘nosti tog produkta nisu dostupni.
Druge toksikološke informacije: Svojstva koja moraju biti sprijec˘ena na temelju sastojaka preparata:
Nakon uzimanja vecih kolicina: proljev.
Drugi podaci: Sproduktom se treba postupati pazljivo, kao sto je to uobic˘ajeno za postupanje s kemikalijama.

12. Ekološke informacije

Ekoloski ucinci: Nisu dostupni
Daljni ekoloski podatci: Ne ocekuju se ekoloski problemi, ako so produkt upotrebljava pazljivo.

13. Vaz˘nost odlaganja

Produkt:
Kemikalije se trebaju odlagati u skladu s odgovarajuc´im nacionalnim propisima. Na adresi www.retrologistik.de mogu se nacine informacije o supstancama i drz˘avama ili imena kontakt osoba
Pakiranje:
Pakiranja Merckovih produkata trebaju se odlagati u skladu s pravilima pojedinih zemalja ili moraju proci kroz sustav povratka ambalaze. Na adresi www.retrologistik.de mogu se na˘i i specificne informacije vezane pravila u pojedinim zemljama ili imena kontakt osoba.

14. Informacije o transportu

Nije predmet transportnih pravila

15. Informacije o propisima

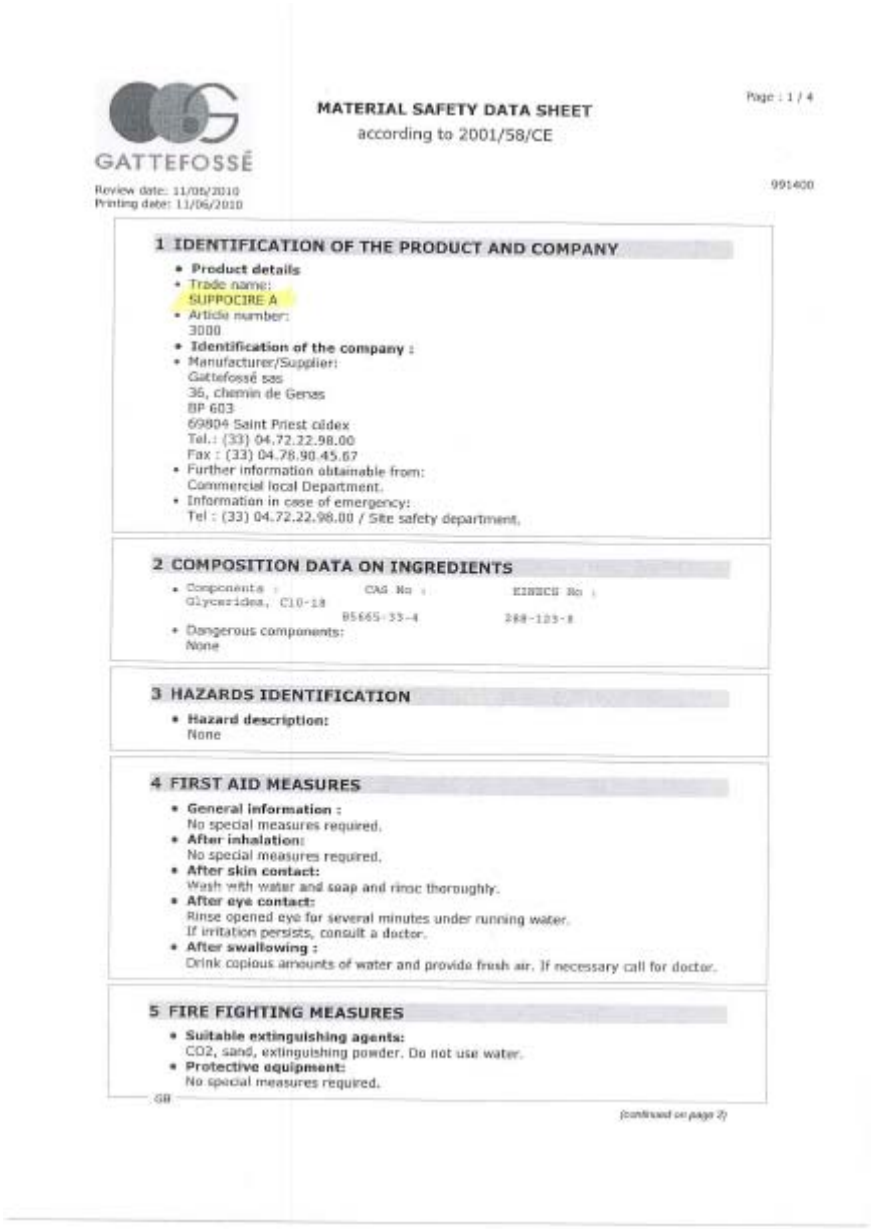
Oznac˘avanje prema EC propisima

Simbol:	---
R-oznake:	---
S-oznake:	---

16. Ostale informacije

Razlog za promjenu
Poglavlje 1: promjene imena produkata.
Generalna promjena parametara.
Regionalno zastupstvo:
Merck d.o.o. * Andrije Hebranga 32 * HR-10000 Zagreb * Tel.: 385 (01) 4864 105/106 * Fax: 385 (01) 4864 191 * e-mail: merck@merck.hr

Ovdje sadrz˘ane informacije temelje se na našim dosadašnjim saznanjima. Karakteriziraju produkt s obzirom na odgovarajuc´e mjere sigurnosti. Ne predstavljaju garanciju za svojstva produkta.



GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET
according to 2001/58/CE

Page : 1 / 4

Review date: 11/05/2010
Printing date: 11/06/2010

991400

1 IDENTIFICATION OF THE PRODUCT AND COMPANY

- **Product details**
- Trade name:
  SUPPOCIRE A
- Article number:
  3000
- **Identification of the company :**
- Manufacturer/Supplier:
  Gattefossé sas
  36, chemin de Genas
  BP 603
  69804 Saint Priest cédex
  Tel. : (33) 04.72.22.98.00
  Fax : (33) 04.78.90.45.67
- Further information obtainable from:
  Commercial local Department.
- Information in case of emergency:
  Tel : (33) 04.72.22.98.00 / Site safety department.

2 COMPOSITION DATA ON INGREDIENTS

- Components : CAS No : EINECS No :
  Glycerides, C10-18 85665-33-4 288-123-8
- Dangerous components:
  None

3 HAZARDS IDENTIFICATION

- **Hazard description:**
  None

4 FIRST AID MEASURES

- **General information :**
  No special measures required.
- **After inhalation:**
  No special measures required.
- **After skin contact:**
  Wash with water and soap and rinse thoroughly.
- **After eye contact:**
  Rinse opened eye for several minutes under running water.
  If irritation persists, consult a doctor.
- **After swallowing :**
  Drink copious amounts of water and provide fresh air. If necessary call for doctor.

5 FIRE FIGHTING MEASURES

- **Suitable extinguishing agents:**
  CO2, sand, extinguishing powder. Do not use water.
- **Protective equipment:**
  No special measures required.

GB

(continued on page 2)

GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET
according to 2001/58/CE

Review date: 11/06/2010
Printing date: 11/06/2010

991400

PRODUCT : SUPPOCIRE A

(continued of page 1)

6 ACCIDENTAL RELEASE MEASURES

- **Person-related safety precautions:**
  No necessary
  Particular danger of slipping on leaked/spilled product.
- **Measures for environmental protection:**
  Do not allow product to reach sewage system or any water course.
- **Measures for cleaning/collecting:**
  Allow to solidify. Pick up mechanically.

7 HANDLING AND STORAGE

- **Handling:**
- Information for safe handling:
  No special measures required.
- Information about fire - and explosion protection:
  Keep ignition sources away - Do not smoke.
- **Storage:**
- Requirements to be met by storerooms and receptacles:
  No special requirements.

8 EXPOSURE CONTROLS AND PERSONAL PROTECTION

- General protective and hygienic measures:
  The usual precautionary measures are to be adhered to when handling chemicals.
- Breathing equipment : No necessary
- Hand protection : No necessary
- Eye protection : No necessary
- Body protection : Protective work clothing

9 PHYSICAL AND CHEMICAL PROPERTIES

Form:	waxy solid
Colour:	Light yellow
Odour:	Light
Melting point/Melting range:	39°C - 46°C (RIGHT CAPILLARY)
Flash point:	150°C
Self igniting :	Product is not self-igniting
Solubility in / Miscibility with water:	Insoluble.
organic solvents:	Soluble in many organic solvents.

10 STABILITY AND REACTIVITY

- **Thermal decomposition / conditions to be avoided:**
  No decomposition if used according to specifications.
- Dangerous reactions
  Reacts with strong acids and oxidizing agents.
- **Dangerous decomposition products:**
  Incomplete combustion releases monoxyd carbon and dioxyd carbon.

GB

(continued on page 3)

GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET
according to 2001/58/CE

991400

Review date: 11/06/2010
Printing date: 11/06/2010

PRODUCT : SUPPOCIRE A

(continued of page 2)

11 TOXICOLOGICAL INFORMATION

- Acute toxicity by oral route :
- Result : DL 0 : 20 ml/kg
Test realised on qualities AI, AP and CM.
- Expert conclusion : Non toxic
- Primary cutaneous irritation :
- Concentration : Pure
- Result : 0,17 (TOX 7734)
Test realised on quality CM.
- Expert conclusion : Very well tolerated
- Ocular irritation (OI) :
- Concentration : Pure
- Result : 5,83 (TOX 7734)
Test realised on quality CM.
- Expert conclusion : Well tolerated
- Rectal tolerance (RT) :
- Expert conclusion :
Well-tolerated to very well-tolerated.
Test realised on qualities AI, AM, AS2X, BML and NB.

12 ECOLOGICAL INFORMATION

- General notes:
At present there are no ecotoxicological assessments.
Its behaviour in environment is likely to vegetal oils : biodegradable

13 DISPOSAL CONSIDERATIONS

- Recommendation about product :
Must be disposed of an incinerator.
- Recommendation:
Disposal must be made according to official regulations.

14 TRANSPORT INFORMATON

- **Land transport ADR/RID (cross-border)**
Not restricted
- **Inland shipping ADN:**
Not restricted
- **Maritime transport IMDG:**
Not restricted
- **Air transport ICAO-TI and IATA-DGR:**
Not restricted

15 REGULATORY INFORMATION

- **Labelling according to EU guidelines:**
The substance is not subject to classification according to the Directives 67/548/EEC and 88/379/EEC.
All compounds of the substance are recorded into european inventory EINECS (European Inventory of Existing Chemical Substances)-Directives 79/831/EEC, sixth modification of directive 67/548/EEC.
- **International rules :**

(continued on page 4)

GB

GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET
according to 2001/58/CE

991403

Review date: 11/06/2010
Printing date: 11/06/2010

PRODUCT : SUPPOCIRE A

(continued of page 3)

- - USA :
  All compounds of the substance are recorded in the US inventory : TSCA (Toxic Substance Control Act).
- - Germany :
  Wassergefährdungsklasse (WGK) : (no polluting)

16 OTHER INFORMATION

Regulatory requirements relative to the distribution of this MSDS : In accordance with the regulatory requirements, all information in the MSDS must be transmitted by the MSDS recipient to the health authorities, to any party receiving the products and to any other person likely to be exposed to the products.
Asterisks on life show modifications with regard to last chemical safety data sheet.

- **Liability clause :**
  The information contained in this data sheet is based on our knowledge of the related product on the date indicated, but does not amount to a guarantee in respect of the product's properties and does not give rise to any contractual legal tie. This information is given in utmost good faith. It cannot substitute for indispensable preliminary tests that must be conducted to ensure product suitability for each intended use. The user's attention is also drawn to the possible risks incurred if a product is used for a purpose other than its designed purpose. This data sheet does not under any circumstance replace knowledge and application by the user of all laws and regulations relevant to his own operations. The user shall be solely liable for the precautions taken relevant to the use made of the products. The list of related laws and regulations is given simply to help the user to fulfil the obligations incumbent upon him for use of the product. This must not be considered an exhaustive list and does not exempt the user from ensuring that he may possibly come under other obligations pursuant to laws or regulation other than those indicated relating to the possession and manipulation of the product for which he shall be solely liable.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 12.11.2010 Version 8.6

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Catalogue No. 108070

Product **name** **Talc suitable** for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP

REACH Registration Number A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses Pharmaceutical production, Cosmetic raw material
For additional information on uses please refer to the Merck Chemicals portal (www.merck-chemicals.com).

1.3 Details of the supplier of the safety data sheet

Company Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0
Responsible Department EQ-EPS * e-mail: prodsafe@merck.de

1.4 Emergency telephone number

Please contact the regional Merck representation in your country.

2. Hazards identification

2.1 Classification of the substance or mixture

This substance is not classified as dangerous according to European Union legislation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a dangerous substance according to GHS.

CAS-No. 14807-96-6

Labelling (67/548/EEC or 1999/45/EC)

The product does not need to be labelled in accordance with EC directives or respective national laws.
EC-No. 238-877-9

2.3 Other hazards

None known.

3. Composition/information on ingredients

Formula 3MgO*4SiO *H O

CAS-No.	14807-96-6
EC-No.	238-877-9
Molar mass	379,27 g/mol

4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

After skin contact: wash off with plenty of water. Remove contaminated clothing.

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist.

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed irritant effects

4.3 Indication of immediate medical attention and special treatment needed

No information available.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Not combustible.

5.3 Advice for firefighters

none

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid generation of dusts; do not inhale dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

6.2 Environmental precautions

No special precautionary measures necessary.

6.3 Methods and materials for containment and cleaning up

Observe possible material restrictions (see sections 7.2 and 10.5).

Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

Indications about waste treatment see section 13.

7. Handling and storage

7.1 Precautions for safe handling

Observe label precautions.

7.2 Conditions for safe storage, including any incompatibilities

Tightly closed. Dry.

Store at +5°C to +30°C.

7.3 Specific end uses
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. Exposure controls/personal protection
8.1 Control parameters

8.2 Exposure controls
Engineering measures
Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures
Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.
Hygiene measures
Wash hands before breaks and at the end of workday.
Eye/face protection
Safety glasses
Hand protection
not required
Respiratory protection
required when dusts are generated.

9. Physical and chemical properties
9.1 Information on basic physical and chemical properties

Form	solid
Colour	white
Odour	odourless
Odour Threshold	No information available.
pH	7,0 - 9,0 at 50 g/l 20 °C (slurry)
Melting point	> 1.300 °C
Boiling point	Noinformation available
Flash point	dose not flash
Evaporation rate	Noinformation available
Flammability (solid, gas)	Noinformation available

No information available.

Lower explosion limit	
Upper explosion limit	not combustible
Vapour pressure	ca.450 kg/m³
Relative vapour density	
Relative density	
Water solubility	
Partition coefficient: n-octanol/water	
Autoignition temperature	
Decomposition temperature	
Viscosity, dynamic	
Explosive properties	
Oxidizing properties	

9.2 Other data

Ignition temperature	
Bulk density	

not applicable
not applicable

No information available.
No information available

ca.2,75 g/cm³
at 20 °C

at 20 °C
insoluble

No information available.

No information available.

No information available.

No information available.

No information available.

10. Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

no information available

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

no information available

11. Toxicological information

11.1 Information on toxicological effects

Skin irritation
slight irritation
Eye irritation
slight irritation
Genotoxicity in vitro
Ames test
Result: negative
(Lit.)
Specific target organ toxicity - single exposure
The substance or mixture is not classified as specific target organ toxicant, single exposure.
Specific target organ toxicity - repeated exposure
The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Aspiration hazard
No aspiration toxicity classification

11.2 Further information

Further information
Quantitative data on the toxicity of this product are not available.
Inhalation of the dusts should be avoided as even inert dusts may impair respiratory organ functions.
Further data:
No toxic effects are to be expected when the product is handled appropriately.

12. Ecological information

12.1 Toxicity

Toxicity to fish
LC50
Species: Danio rerio (zebra fish)
Dose: > 100.000 mg/l
Exposure time: 24 h
(IUCLID)

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

14. Transport information

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substanceor mixture

EU regulations

Major Accident Hazard	96/82/EC
Legislation	Directive 96/82/EC does not apply

National legislation

Storage class VCI	10 - 13 Other liquids and solids

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16. Other information

Training advice

Provide adequate information, instruction and training for operators.

Regional representation: This information is given on the authorised Safety Data Sheet for your country.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

PARAFLUID

EC-SAFETY DATA SHEET ACCORDING TO 1907/2006, Article 31
VASELINE WHITE PH.EUR., TYPE CD 806

1 Identification of the substance/preparation and of the company / undertaking

Name of product:
VASELINE WHITE PH.EUR., TYPE CD 806

Manufacturer/Supplier:
PARAFLUID MINERALOELGESELLSCHAFT MBH
Überseering 9
D-22297 Hamburg
Tel.. +49 (0) 637 04-00
Fax: +49 (0) 637 04-125

Emergency phone number:
+ 49-(0)-30/30686 790 –
Advice Centre of Synonyms of Poisoning, 14050 Berlin, Germany

Application of the substance/the preparation
Skin cosmetics
Additive for cosmetic or pharmaceutic preparations
Lubricant

2 Hazardous identification

Hazard description:
Not applicable.
Information concerning particular hazards for human and environment.
Not applicable.

3 Composition/information of ingredients

Chemical characterization:

CAS No.	Description
	White soft paraffin (petrolatum)

4 First aid measures

After inhalation:
Supply fresh air; consult doctor in case of complaints
After skin contact:
After contact with the molten product, cool rapidly with cold water.
Cover would with a sterile dressing.
Seek medical treatment:
After eye contact:
Rinse opened eye for several minutes under running water.
Seek medical treatment:
After swallowing:
Do not induce vomiting; call for medical help immediately.

6 Fire-fighting measures

Suitable extinguishing agents:
CO2, sand, extinguishing powder. Do not use water.
Foam

PARAFLUID

EC-SAFETY DATA SHEET ACCORDING TO 1907/2006, Article 31
VASELINE WHITE PH.EUR., TYPE CD 806

6 Accidental release measures
Person-related safety precautions:
Particular danker of slipping on leaked/spilled product.
Measures for environmental protection:
Do not allow to enter sewers/surface or ground water.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
Inform respective authorities in case of seepage into water course or sewage system
Measures for cleaning/collecting:
Pick up mechanically.
Additional information: No dangerous substances are released.

7 Handling and storage
Handling:
Information for safe handling: No special measures required.
Information about fire – and explosion protection: Fumes can combine with air to foam an explosive mixture.

Storage:
Requirements to be met by storerooms and receptacles:
No special requirements.
Information about storage in one common storage facility:
Store away from oxidizing agents.
Further information about storage conditions:
Store in cool, dry conditions in well sealed receptacles.
Protect from exposure to the light:
Storage class: 11

8 Exposure controls/personal protection
Additional information about design of technical facilities:
No further data; see item 7:

Ingredients with limit values that require monitoring at the workplace:
Not required.
Additional information:
The lists valid during the making were used as basis.

Personal protective equipment:
General protective and hygienic measures:
The usual precautionary measures are to be adhered to when handling chemicals.
Do not eat, drink, smoke or sniff while working.
Respiratory protection:
Not required.
Protection of hands:
Oil resistant gloves
Material of gloves:
Nitrile rubber; NBR
PVC gloves

PARAFLUID

EC-SAFETY DATA SHEET ACCORDING TO 1907/2006, Article 31
VASELINE WHITE PH.EUR., TYPE CD 806

Penetration time of glove material
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection:
Safety glasses
Body protection:
Oil resistant protective clothing

9 Physical and chemical properties

General information

Form:	Pasty
Colour:	White
Odour:	Odourless

Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Congealing point:	50-55 °C
Flash point:	210 °C
Flammable (solid, gaseous)	Product is not flammable.
Danger of explosion:	Product does not present an explosion hazard
Vapour pressure at 20 °C:	<0.01 hPa
Density:	(80 °C) 790-840 kg/m3
Solubility in / Miscibility with water:	Insoluble.
Viscosity:	
Kinematic:	(100 °C) 5-9 mm2/s

10 Stability and reactivity
Thermal decomposition / conditions to be avoided:
No decomposition if used according to specifications.
Dangerous reactions
No dangerous reactions known.
Dangerous decomposition products:
No dangerous decomposition products known.

11 Toxicological information
Acute toxicity:
Primary irritant effect:
on the skin:
No irritant effect.
on the eye:
No irritating effect.
Sensitization:
No sensitizing effects known.

3

PARAFLUID

EC-SAFETY DATA SHEET ACCORDING TO 1907/2006, Article 31
VASELINE WHITE PH.EUR., TYPE CD 806

Additional toxicological information:
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
The substance is not subject to classification according to the latest version in the EU lists.

12 Ecological information
Information about elimination (persistence and degradability): The product is not easily, not potentially degradable.
General notes: Generally not hazardous for water

13 Disposal considerations
Product:
Recommendation
Can be reused after reprocessing.
Smaller quantities can be disposed of with household waste.
European waste catalogue
05 01 06 oily sludges from maintenance operations of the plant or equipment
Unpleaned packaging:
Recommendation:
Packaging may be reused or recycled after cleaning.

14 Transport information
Land transport ADR/RID (cross-border)
ADR/RID class: -

Maritime transport IMDG:
Marine pollutant: No

Transport/Additional information: Not dangerous according to the above specifications.

16 Regulatory information
Labelling according to EU guidelines:
Observe the general safety regulations when handling chemicals.
The substance is not subject to classification according the EU lists and other sources of literature known to us.

Special labelling of certain preparations.
Safety data sheet available for professional user on request.

National regulations:
Other regulations, limitations and prohibitive regulations INCI-Name: Petrolatum

18 Other information
This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Revision: 18.11.2009
Printing date: 03.05.2011

4

Drug'on

SAFETY DATA SHEET

according to the Global Harmonized System

Verapamil hydrochloride

1. Identification of the substance/preparation and of the company/undertaking

Use of the Substance/Preparation	Pharmaceutical agent (80%)
Product code	6000
Company/Undertaking Identification	Drug'On Pharma Switzerland AG Oristalstrasse 65 CH-4410 Liestal Switzerland Ph : +41 61 925 05 05 Fax : +41 61 925 03 42
Emergency telephone number	145 (Swiss Tox Center)
Revision Date	07.12.2010
Version	GHS 1 (engl.)

2. Hazards identification

DANGER!

Acute toxicity, oral, Cat. 3
Serious eye damage/eye irritation, Cat. 1

3. Composition/information on ingredients

Components		Health hazards	CAS	REACH No.
Verapamil hydrochloride	100%	TAOr3, CEy1	152-11-4	

4. First aid measures

Inhalation	Move to fresh air. Consult a physician after significant exposure.
Skin contact	Wash off immediately with soap and plenty of water.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist.
Ingestion	Immediately give plenty of water (if possible charcoal slurry). Consult a physician for severe cases.

5. Fire-fighting measures

Suitable extinguishing media	Use dry chemical, CO2, water spray or alcohol foam.
Extinguishing media which must not be used for safety reasons	High volume water jet.
Specific hazards	The product is not flammable.
Special protective equipment for firefighters	Standard procedure for chemical fires.
Specific methods	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

6. Accidental release measures

Personal precautions	Use personal protective equipment.
Environmental precautions	Do not flush into surface water or sanitary sewer system. Local authorities should be advised if significant spillages cannot be contained.
Methods for cleaning up	After cleaning, flush away traces with water. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Sweep up and shovel into suitable containers for disposal.

7. Handling and storage

Handling	Wear personal protective equipment. Handle and open container with care.
Storage	Keep at temperatures between 15 and 30 °C. Keep away from direct sunlight. Store in a place accessible by authorized persons only.

8. Exposure controls / personal protection

Occupational exposure controls	Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. Handle in accordance with good industrial hygiene and safety practice. Contaminated work clothing should not be allowed out of the workplace.
Personal protection equipment	
Respiratory protection	In the case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.
Hand protection	Gloves made of Nitril.
Eye protection	Safety glasses with side-shields conforming to EN 166. Eye wash bottle with pure water.
Skin and body protection	Wear as appropriate: Impervious clothing.

9. Physical and chemical properties

Form	Crystalline.
Colour	White.
Odour	None.
Physical and chemical properties	pH: not applicable Flash point: does not ignite. Water solubility: soluble Fat solubility: partly soluble Melting point/range: 144 °C. Bulk density 0.5 - 0.6 g/ml.

10. Stability and reactivity

Stability	No decomposition if used as directed.
Conditions to avoid	Do not freeze. Heating can release hazardous gases.
Hazardous decomposition products	None under normal use.

11. Toxicological information

Acute toxicity	LDLO/oral/rat = 114 mg/kg. LC50/inhalation/rat >= 2 mg/kg .
Local effects	Risk of serious damage to eyes. May cause skin irritation with susceptible persons. Toxic by inhalation, in contact with skin and if swallowed. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Long term toxicity	Symptoms may be delayed.
Sensitization	None.
Further information	Use of alcoholic beverages may enhance toxic effects.

12. Ecological information

Ecotoxicity	LC50/96h/fish < 10 mg/l .
Persistence / degradability	Readily biodegradable.
Bioaccumulative potential	Does not bioaccumulate.

13. Disposal considerations

Waste from residues / unused products	Taking into account local regulations the product may be disposed of as waste water after neutralisation. Dispose of as hazardous waste in compliance with local and national regulations. Dispose of wastes in an approved waste disposal facility.
Contaminated packaging	Offer rinsed packaging material to local recycling facilities.

14. Transport information

ADR/RID	Proper shipping name TOXIC SOLID, ORGANIC, N.O.S. (Verapamil hydrochloride) UN No 2811. Class 6.1. Packing group III. ADR/RID-Labels 6.1. Classification code T2. Risk No. 60. Limited quantity LQ9. Tunnel code E
IMO	Proper shipping name Toxic solid, organic, n.o.s. (Verapamil hydrochloride) UN No 2811. Class 6.1. Packing group III. ADR/RID-Labels 6.1. Limited quantity 5 kg. EmS F-A, S-A. Marine Pollutant no

ICAO	Proper shipping name Toxic solid, organic, n.o.s. (Verapamil hydrochloride) UN No 2811. Class 6.1. Packing group III. Packing instruction (passenger aircraft): 619 (100 kg). Packing instruction (LQ): Y619 (10 kg). Packing instruction (cargo aircraft): 619 (200 kg).

15. Regulatory information

GHS-Classification	
Signal Word	DANGER!
Hazard Statements	Toxic if swallowed. Causes serious eye damage.
Precautionary statements	Wear protective gloves/ eye protection/ face protection. Do not eat, drink or smoke when using this product. IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Dispose of contents/ container to an approved waste disposal plant.
GHS product identifier	Verapamil hydrochloride, CAS-No. 152-11-4
EC-Symbol(s)	T - Toxic.
R-phrase(s)	R25: Toxic if swallowed. R41: Risk of serious damage to eyes.
S-phrase(s)	S22: Do not breathe dust. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39: Wear suitable protective clothing, gloves and eye / face protection. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Regulatory information	The product is classified and labelled in accordance with Directive 1999/45/EC.

16. Other information

Recommended use	Restricted to professional users. Attention - Avoid exposure - obtain special instructions before use.
GHS-Classification	TAOr3: Acute toxicity, oral, Cat. 3 CEy1: Serious eye damage/eye irritation, Cat. 1
Further information	Take notice of the directions of use on the label.

Disclaimer	The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release. It is not to be considered a warranty or quality specification.

Disclaimer	The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release. It is not to be considered a warranty or quality specification.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

DSM

Ascorbic Acid 95% Granulation 5007747

Version 1.0 Revision Date 17.06.2010 Print Date 28.04.2011

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product information

Trade name	:	Ascorbic Acid 95% Granulation
Use of the Substance/Mixture	:	Ingredient for capsules and/or tablets
Company	:	DSM Nutritional Products Hungary Kft. Japán fasor 4. HU-2367 Újhartyán
Telephone	:	+3629572400
Telefax	:	+3629572451
Emergency telephone	:	0036-29-572-400 / +41 62 866 2314 This telephone number is available during office hours only.
E-mail address Responsible/issuing person	:	sds.nutritionalproducts@dsm.com

2. HAZARDS IDENTIFICATION

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

Additional hazards and advice

Risk of dust explosion.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Brief description of the product	:	Mixture (preparation) containing active ingredient and auxiliary substance
Remarks	:	No dangerous ingredients according to Regulation (EC) No. 1907/2006

Further ingredients

Chemical Name	CAS-No. EC-No. Registration number	Classification	GHS Classification	Concentration [%]
ascorbic acid	50-81-7 200-066-2			>= 95 - < 100

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SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

DSM

Ascorbic Acid 95% Granulation 5007747

Version 1.0 Revision Date 17.06.2010 Print Date 28.04.2011

4. FIRST AID MEASURES

General advice	:	No hazards which require special first aid measures.
Inhalation	:	Move to fresh air in case of accidental inhalation of dust or fumes from overheating or combustion. If symptoms persist, call a physician.
Skin contact	:	Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water.
Eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing.
Ingestion	:	Rinse mouth with water and drink plenty of water afterwards. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water Foam
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Consider dust explosion hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	:	Avoid dust formation.
Environmental precautions	:	Try to prevent the material from entering drains or water courses. No special environmental precautions required.
Methods for cleaning up	:	Sweep up and shovel.

7. HANDLING AND STORAGE

Handling

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SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

DSM

Ascorbic Acid 95% Granulation 5007747

Version 1.0 Revision Date 17.06.2010 Print Date 28.04.2011

Advice on safe handling	:	For personal protection see section 8. No special handling advice required.
Advice on protection against fire and explosion	:	Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.

Storage

Requirements for storage areas and containers	:	Protect from humidity.
	:	Keep container tightly closed and dry.
Advice on common storage	:	No special restrictions on storage with other products.
Storage temperature	:	< 25 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures

For technical measures see section 7.

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required. In case of high dust concentration use a dust mask applicable to local conditions.
Hand protection	:	Glove material: for example nitrile rubber
Eye protection	:	Safety glasses
Skin and body protection	:	Protective suit
Hygiene measures	:	General industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	:	powder, granular
Colour	:	white - off-white
Particle size	:	<= 15 % <= 0,075 mm

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SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

DSM

Ascorbic Acid 95% Granulation 5007747

Version 1.0 Revision Date 17.06.2010 Print Date 28.04.2011

Safety data

Flash point	:	not applicable
Dust explosion class	:	St1 (Test performed using a similar product.)

10. STABILITY AND REACTIVITY

Conditions to avoid	:	Exposure to air. (as aqueous solution)
		Heat.
Materials to avoid	:	Oxidizing agents
	:	Bases
Thermal decomposition	:	Decomposes on heating. Potential for exothermic hazard Heating can release hazardous gases.
Hazardous reactions	:	Dust may form explosive mixture in air.
	:	Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	:	LD50 (rat): > 5 000 mg/kg (calculated from LD50 of components)
Skin irritation	:	No skin irritation (rabbit, OECD Test Guideline 404, 4 h) Information refers to the main component.
Eye irritation	:	Dust contact with the eyes can lead to mechanical irritation.
Genotoxicity in vivo	:	No indication for human genotoxicity known. Information refers to the main component.
Experience with human exposure	:	RDA (Recommended Daily Allowance), 60 mg Information refers to the main component.
Experience with human exposure: Skin contact	:	May be slightly irritating, especially on damp skin.
Experience with human exposure: Ingestion	:	Oral intake up to 9 g ascorbic acid per day does not produce any serious toxic effects. However, diarrhoea can occur even

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with lower consumption levels.

12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Toxicity to fish : Oncorhynchus mykiss (rainbow trout)
LC50 (96 h) 1 020 mg/l
Information refers to the main component.
(OECD Test Guideline 203)

Elimination information (persistence and degradability)

Biodegradability : Well inherently biodegradable.
100 % (15 d)
97 %, (5 d)
(OECD Test Guideline 302B)
Information refers to the main component.

Further information on ecology

Additional ecological information : There is no data available for this product.

13. DISPOSAL CONSIDERATIONS

Product : Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. TRANSPORT INFORMATION

ADR
Not dangerous goods

IATA
Not dangerous goods

IMDG
Not dangerous goods

RID
Not dangerous goods

Not classified as dangerous in the meaning of transport regulations.

15. REGULATORY INFORMATION

Labelling according to EC Directives

1999/45/EC

Further information : The product does not need to be labelled in accordance with EC directives or respective national laws.

16. OTHER INFORMATION

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Во ПЦ Фармација како енергенси се користат
Електрична енергија за

- Работа на машини во производство
- Системи за ладење (1 према 3 , а некаде 1 према 5 во однос на вложена електрична енергија према добиена ладилна енергија, со користење на еколошко средство за ладење Р 134 А) во производство и останати помошни објекти
- Клима уреди (дополнително ладење-греење на простории)
- Осветлување

Природен гас за

- Производство на водена пареа за загревање во производство и останати објекти
- Производство на водена пареа за потреби на производни процеси

Мазут
Има само еднонеделна залиха во случај на немање довод на природен гас.

Гориво

	m^3/god.
Природен гас	1.000.000

Заостанато гориво за резерва

	t/god.
Мазут М2	200.000

Енергија

	kWh/god.
Електрична енергија	7.176.441

Вода

	m^3/god.
Вода	144.866

АЛКАЛОИД СКОПЈЕ

Safety Data Sheet – Безбедносен лист со податоци

Според **Регулативата (EC) No. 1907/2006**

Изработен на: 23.11.2010 год.
Верзија: 2

1. ПОДАТОЦИ ЗА ПРОИЗВОДОТ И ЗА КОМПАНИЈАТА

Име на производот: **Етанол 96% Ph Eur**
Производител: Алкалоид АД, А. Македонски 12, Скопје, Р. Македонија
Телефон: 02 3104 000
Телефон во случај на опасност: 02 3104 392

2. ПОДАТОЦИ ЗА ОПАСНОСТ

2.1. Совети за опасност за човекот и околината

GHS Класификација
Запалива течност, Категорија 2

3. СОСТАВ / ПОДАТОЦИ ЗА КОМПОНЕНТИТЕ

Хемиска формула	C_2H_5OH
CAS No.	64-17-5
EC No.	200-578-6
Синоними	етил алкохол
Молекулска маса	46,07 g/mol

4. МЕРКИ ЗА ПРВА ПОМОШ

4.1. Опис на мерки за помош, во итни ситуации

При контакт со кожата: измијте со многу вода. Отстранете ја контаминираната облека.

При контакт со очите: исплакнете ги со многу вода. Повикајте офталмолог.

Во случај на проголтување: веднаш дајте вода (најмногу 2 чаши). Консултирајте лекар.

Во случај на вдишување: свеж воздух. Повикајте лекар.

5. ПОДАТОЦИ ЗА ПОЖАР И ЗА ЕКСПЛОЗИЈА

5.1. *Соодветни средства за гаснење*
Јаглероден диоксид (CO_2), пена, сув прав.

5.2. Специфични опасности при гаснење пожар

Производот е запалив. Испарувањата се потешки од воздухот и можат да се шират. Во случај на пожар, можно е развивање на опасни, запаливи гасови и испарувања. На собна температура, создавање на експлозивни смеси со воздухот.

5.3. *Специјална заштитна опрема за пожарникари*

Да не се престојува во опасната зона без апарат за дишење.

Дополнителни податоци

Затворените контејнери, кои биле изложени на оган, изладете ги со прскање со вода. Погрижете се водата што сте ја употребиле при гаснење на пожарот да не ги загади водените површини или составот бна подземните води.

6. МЕРКИ ПРИ СЛУЧАЈНО ИСТЕКУВАЊЕ

6.1. Мерки за лична заштита

Избегнете контакт со супстанцијата. Не ги вдишувајте испарувањата.
Овозможете влез на свеж воздух во затворени простории.

6.2. Мерки за заштита на околината

Да не се истура во одводните канали. Експлозивни својства.

6.3. Методи за чистење

Соберете со материјал кој апсорбира течности. Со отпадот постапете согласно прописите за складирање на хемиски отпад. Исчистете ја зафатената површина.

7. РАКУВАЊЕ И СКЛАДИРАЊЕ

7.1. Ракување

Совети за заштита против пожари и експлозии

Чувајте го производот подалеку од отворен оган, топли површини и извори на палење. Превземете ги потребните мерки против статичко празнење.

7.2. Складирање

Останати податоци за услови на складирање

Добро затворено, во добро проветрена просторија, подалеку од извор на искрење или топлина.

Без ограничување.

8. КОНТРОЛА НА ИЗЛОЖЕНОСТ / ЛИЧНА ЗАШТИТА

8.1. *Опрема за лична заштита*

Заштитната облека мора да биде соодветна за секое работно место, во зависност од концентрацијата и количината од опасните материи со кои се ракува.Отпорноста на заштитната облека кон хемикалии, треба да биде специфицирана од добавувачот.

8.2. Заштита на органите за дишење

Потребно е доколку се појават испарувања.

Препорачан тип на филтер: филтер A (согласно DIN 3181) за испарувања на органски компоненти.

8.3. Заштита на раце

при полн контакт

материјал од кој се

направени ракавиците:	бутил-гума
дебелина на ракавиците:	0,7 mm
време на продирање на хемикалиите:	> 480 min

контакт при прскање

материјал од кој се направени ракавиците:	нитрил-гума
дебелина на ракавиците:	0,40 mm
време на продирање на хемикалиите:	> 120 min

Заштитните ракавици кои се употребуваат треба да бидат во согласност со регулативите на ЕС директивата 89/686/ЕЕС и стандардот EN374.

8.4. Заштита за очи
Потребна.

8.5. Заштитни мерки
Облека отпорна на оган, антистаична заштитна облека.

8.6. Хигиенски мерки
Променете ја загадената облека. Нанесете заштитна крема. Убаво измијте ги рацете, после работа со супстанцијата.

9. ФИЗИЧКИ И ХЕМИСКИ СВОЈСТВА

9.1. Карактеристики	бистра, безбојна течност со карактеристичен мирис
9.2. Киселост или алкалност	најмногу 30 ppm
9.3. Релативна густина	0,8051-0,8124 g/cm^3
9.4. Апсорбанса	по пропис
9.5. Испарливи онечиостувања	по пропис
9.6. Содржина	95,1-96,9 % (W/W)
9.7. Остаток по испарување	најмногу 25 ppm m/w

10. СТАБИЛНОСТ И РЕАКТИВНОСТ

10.1. *Услови кои треба да се избегнуваат*
Загревање.

10.2. *Материи кои треба да се избегнуваат*
Опасност од експлозија со:
нема достапни податоци.

Опасност од запалување или од создавање на запаливи гасови и испарувања со:
алкални метали, земноалкални метали, алкални оксиди, јаки оксидативни средства, халоген-халоген комбинации, хромил-хлорид, етилен оксид, флуор, перхлорати, калиум перманганат, сулфурна киселина, перхлорна киселина, перманганатна киселина, азотна киселина, фосфорни оксиди, водороден пероксид, азот диоксид.

10.3. *Штетни продукти при распаѓање*
Нема достапни информации.

Дополнителни податоци
Несоодветни материјали за работа: пластика, гума

Испарувањата можат да создадат експлозивни смеси со воздухот.

11. ТОКСИКОЛОШКИ ПОДАТОЦИ

11.1. *Акутна орална токсичност*
LD50 (смртна доза) стаорец
Доза: 6200 mg/kg
Симптоми: повраќање, мачнина.

11.2. *Акутна токсичност при вдишување*
LC50 (смртна доза) стаорец
Доза: 95,6 mg/l
Симптоми: повраќање, мачнина.

11.3. *Акутна токсичност на кожата*
Симптоми: воспаление на кожата.

11.4. *Иритација на кожата*
зајак
Резултат: нема иритација.

11.5. *Иритација на очите*
зајак
Резултат: нема иритација.

11.6. *Генотоксичност ин витро*
Резултат: негативен.

11.7. *Акутна токсичност при вдишување*
LC50 стаорец
Симптоми: слаба иритација на слузницата, опасност од апсорпција.

Дополнителни информации
Систематични ефекти: еуфорија

При апсорпција на поголеми количини:
Вртоглавица, зашеметеност, наркоза, респираторна парализа.
Ракувајте со производот во согласност со добрата индустриска хигиена и практика.

12. ЕКОЛОШКИ ПОДАТОЦИ

Екотоксично дејство
12.1. *Отровно за риби.*
LC50
Доза: 8140 mg/l

12.2. *Отровно за daphnia и за останатите водени без'рбетници.*
EC5, EC50
Доза: 65 mg/l

12.3. *Отровно за алги*
IC5
Доза: 5000 mg/l

12.4. *Отровно за бактерии*
EC5
Доза: 6500 mg/l

Постојаност и распаѓање
Биолошко распаѓање
Големо распаѓање, 94%

Биолошка потрошувачка на кислород (BOD)
930-1670 mg/g

Хемиска потрошувачка на кислород (COD)
1990 mg/g

Теоретска потрошувачка на кислород (ThOD)
2100 mg/g

Дополнителни еколошки податоци
Биолошки ефекти**:**

При високи концентрации:

Штетно дејство кај водените организми.
Кога производот правилно се користи, нема штетно влијание врз растенијата третирани со отпадни води.

Останати еколошки податоци

Не се очекуваат еколошки проблеми, доколку производот се користи внимателно.

13. НАЧИН НА ОТСТРАНУВАЊЕ

Отпадот треба да се отстрани во согласност со националната, регионалната и со локалната регулатива за контрола на животната средина.

14. ИНФОРМАЦИИ ЗА ТРАНСПОРТ

Копнен транспорт:	ADR, RID	UN 1170 ETHANOL, 3, II
Воздушен транспорт:	IATA	UN 1170 ETHANOL, 3, II
Воден транспорт:	IMDG	UN 1170 ETHANOL, 3, II

15. БЕЗБЕДНОСНИ ИНФОРМАЦИИ

Етикетирање согласно GHS

Сигнален збор
Опасност.

Изјави за опасност

H225: Многу запалива течност и испарувања

Изјави за претпазливост

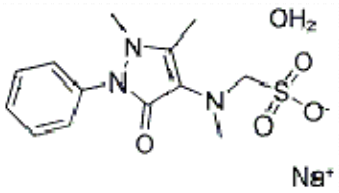
P210: Чувајте го подалеку од топлина/искри/оган/врели површини-
забрането пушење

16. ОСТАНАТИ ИНФОРМАЦИИ

Производот е сигурен под услов да се употребува според пропишаните услови и согласно примената наведена на амбалажата и / или техничките упатства. За било која друга употреба за производот во комбинација со друг производ или процес, одговорноста ја презема корисникот.

Други посебни мерки : нема податоци

5907-38-0(Analgin) Product Description



CAS No. **5907-38-0**

Chemical Name: **Analgin**
CBNumber: CB6715922
Molecular Formula: C13H18N3NaO5S
Formula Weight: 351.35
MOL File:

Analgin Synonyms:

ANALGINE, PHARMA,
Metamizol, Methapyrone,
DIPYRON HYDRATE VETRANAL;,
Metamizole,sodium salt;,
Noramidopyrine methamesulfonate sodium;
Novalgin;
NORAMIDOPYRINI METHANOSULFONATE;
Dipyrone,hydrate

Analgin Property
storage temp. : 2-8°C

Safety
Hazard Codes Xn
Risk Statements 63
Risk Statements 36/37

MEGGLE EIP

Part I

Product Regulatory Datasheet for MicroceLac® 100

Date of issue: 03.11.2009

	Check			Approval
Date of issue				03.11.2009
Electronic Signature				Gabriele Mueller, QA/QM
Date of issue				03.11.2009
Electronic Signature				Egmont Pfeifer, Head BG E&T

MEGGLE, Megglestr. 6–12, D-83512 Wasserburg, Tel. +49 (0) 80 71 / 73-0, Fax +49 (0) 80 71 / 73-444

MEGGLE EIP

PART I for MicroceLac® 100

MEGGLE

This document is part of the MEGGLE EIP (Excipient Information Package).

The MEGGLE EIP is based on the "IPEC Excipient Information Package (EIP): Template and User Guide, 2009" (http://www.ipecamericas.org) and consists of the following documents (each with separate revision cycles):

- **Part I : Product Regulatory Datasheet**
  available for the products:
  - Lactose Monohydrate PhEur
  - Cellactose® 80
  - MicroceLac® 100
  - StarLac®
- **Part II: Manufacturing Site Quality Overview**
- **Part III: Site and Supply Chain Security Overview**

For definitions and glossary please go to the "IPEC Excipient Information Package (EIP): Template and User Guide, 2009" (http://www.ipecamericas.org).

TABLE OF CONTENTS

of "Part I Product Regulatory Datasheet for MicroceLac® 100"

Section 1 – General Product Information

Product Name	**MicroceLac® 100** for oral application. **MicroceLac® 100** is a spraydried mixture of 75 parts Lactose Monohydrate (PhEur) and 25 parts Cellulose Microcristalline (PhEur, USP/NF, JP). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. **MicroceLac® 100** is a coprocessed excipient.
Scope of Document	Oral grade **MicroceLac® 100** as mentioned above.

Section 2 – Manufacturing, Packaging, Release Site and Supplier Information

Site of production, packaging, product release, warehousing	Molkerei MEGGLE Wasserburg GmbH & Co. KG Megglestr. 6-12 83512 Wasserburg Germany Further on referred to as „**MEGGLE**". Employees: • Total: About 850 • In production of pharmaceutical excipients: About 100 • In Quality Unit: About 30 • In R&D for pharmaceutical excipients: About 5 • In Sales of pharmaceutical excipients: About 15 Organigrams can be provided on request.
Other production sites	• Not applicable. No other production sites.

MEGGLE, Megglestr. 6–12, D-83512 Wasserburg, Tel. +49 (0) 80 71 / 73-0, Fax +49 (0) 80 71 / 73-444

Contract labs	• Heavy metals are analysed by the following contract lab: LPU, Labor für Pharmazeutische Qualitätskontrolle und Umweltanalytik (Laboratory for Pharmaceutical Quality Control and Environmental Analysis), Fraunhoferstr. 11a, 82152 Martinsried, Germany • Part of microbiological parameters is analysed by the following contract lab: Lehrstuhl für Hygiene und Technologie der Milch, Tierärztliche Fakultät der LM Universität München, Milchhygiene, Schönleutnerstraße 8 85764 Oberschleißheim, Germany • The contract labs have been qualified. • Responsibility for the outsourced analyses remains with MEGGLE.
Exclusive Distribution Channels	• Not applicable
GMP or GDP compliance statement	• GMP according to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients is installed at MEGGLE. • GDP principles based on the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients are applied to.
Multi purpose site	• The site is a multipurpose site authorized by the German Official Veterinary Authorities according to EC Hygiene Regulation (EC) No. 853/2004 for dairy operation.
Multi purpose equipment	• **MicroceLac® 100** is produced on equipment where mainly excipients based on Lactose Monohydrate PhEur are produced. Cleaning validation is installed.

Section 3 – Physical-chemical Information

CAS Number	CAS Numbers of the components of **MicroceLac® 100:** • Lactose Monohydrate PhEur: 64044-51-5 • Cellulose Microcristalline PhEur, USP/NF, JP: 9004-34-6
EINECS Number	EINECS Numbers of the components of **MicroceLac® 100:** • Lactose Monohydrate PhEur: 200 559 2 • Cellulose Microcristalline PhEur, USP/NF, JP: 23 26 749
Origin Information (synthetic, animal, vegetable, mineral, product of biotechnology, product of fermentation, etc.)	Origin information of the components of **MicroceLac® 100:** • Origin of Lactose Monohydrate PhEur: Animal origin. Lactose Monohydrate PhEur is produced from whey (bovine). • Origin of Cellulose Microcristalline PhEur, USP/NF, JP: Vegetable origin. Origin of Cellulose Microcristalline PhEur, USP/NF, JP is wood.
Synonyms (including INCI name)	Synonyms of the components of **MicroceLac® 100:** • Lactose Monohydrate PhEur: - Milk sugar - O-β-D-Galactopyranosyl-(1→4)-α-D-glucopyranose monohydrate • Cellulose Microcristalline PhEur, USP/NF, JP: E460 i) INCI names of the components of **MicroceLac® 100:** • Lactose Monohydrate PhEur: Lactose • Cellulose Microcristalline PhEur, USP/NF, JP: Cellulose

Brief descriptions of manufacture	<u>Starting materials</u> Starting materials are Lactose Monohydrate PhEur and Cellulose Microcristalline PhEur, USP/NF, JP. • Starting material Lactose Monohydrate PhEur is produced and released by MEGGLE according to MEGGLE QM System. • Starting material Cellulose Microcristalline PhEur, USP/NF, JP: - List of approved suppliers is installed. - Certificate of analysis is provided with each delivery. - On receipt MEGGLE analyses starting material Cellulose Microcristalline PhEur, USP/NF, JP according to defined sample code (frequency, sampling, parameters, methods, limits). - Positive release of Starting material Cellulose Microcristalline PhEur, USP/NF, JP is performed. <u>Water</u> • For production demineralised water made from drinking water according to Directive 98/83/EC is used. • Drinking water comes from own wells. • Water is treated with UV and filtered. No chemical treatment. • Internal and external analytical control of water according to Directive 98/83/EC and defined MEGGLE sample code is installed. <u>Production</u> • **MicroceLac® 100** is a coprocessed excipient produced by spray drying process:

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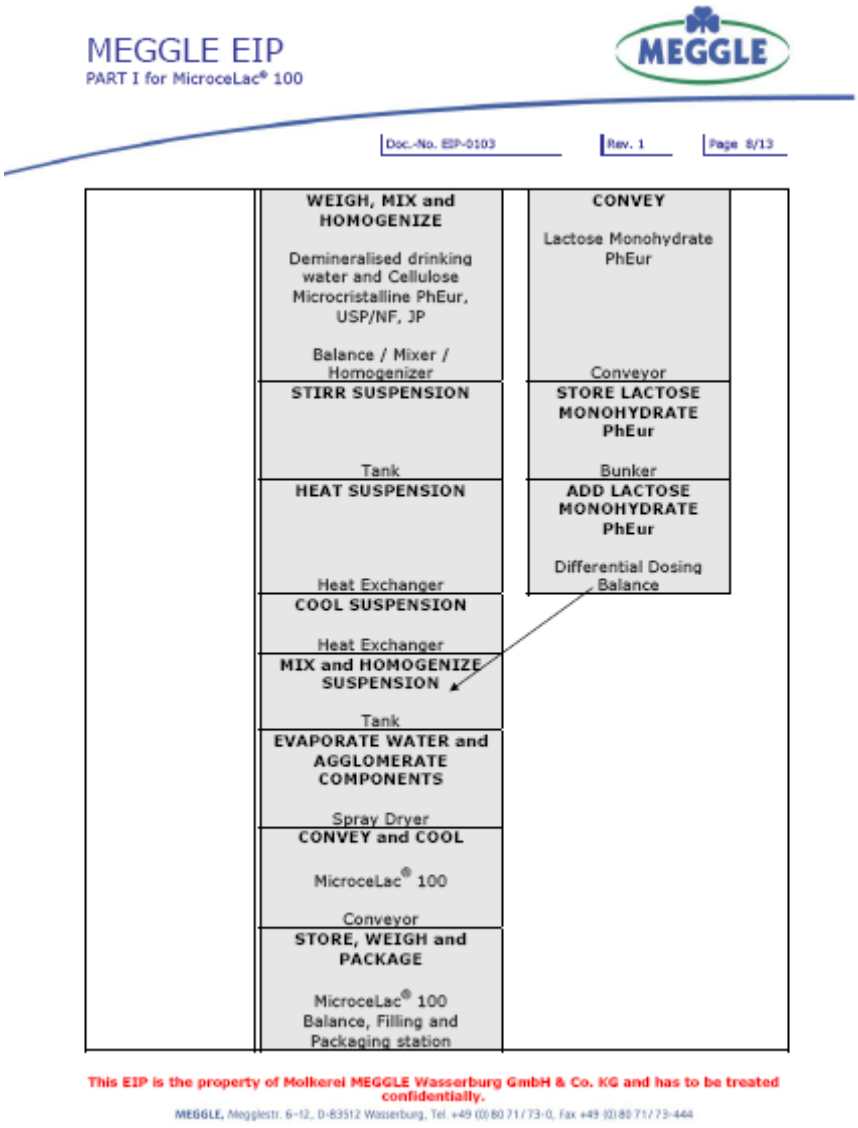
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WEIGH, MIX and HOMOGENIZE
Demineralised drinking water and Cellulose Microcristalline PhEur, USP/NF, JP
Balance / Mixer / Homogenizer
CONVEY
Lactose Monohydrate PhEur
Conveyor
STIRR SUSPENSION
Tank
STORE LACTOSE MONOHYDRATE PhEur
Bunker
HEAT SUSPENSION
Heat Exchanger
ADD LACTOSE MONOHYDRATE PhEur
Differential Dosing Balance
COOL SUSPENSION
Heat Exchanger
MIX and HOMOGENIZE SUSPENSION
Tank
EVAPORATE WATER and AGGLOMERATE COMPONENTS
Spray Dryer
CONVEY and COOL
MicroceLac® 100
Conveyor
STORE, WEIGH and PACKAGE
MicroceLac® 100
Balance, Filling and Packaging station
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	• Continuous production • Closed equipment • Sieve and permanent magnet (9000 Gauss) are installed. Packaging, Labelling • Packaging directly in line after production. • Filtered air and over pressure in the packaging area. • Monitoring of temperature and humidity in packaging area. • Only new packaging. Packaging is not reused. • Labelling of bags: Preprinted bags and printing of lot code during packaging. Warehousing, Transport • No opening of packaging after production. • Electronical control of quarantine/hold/release status in warehouse computer system. • FIFO is performed. • Monitoring of temperature and humidity in the warehouse. • Transport: See Part III of the EIP Quality Control • IPC testing according to defined sample code (frequency, sampling, parameters, methods, limits). • Testing of finished product according to defined sample code (frequency, sampling, parameters, methods, limits). Retained samples Retained samples are kept for shelf life + 1 year. Batch record review • Batch record review is performed by production and QC according to MEGGLE QM System. • Review of production documentation by production foreman and head of production. Documentation in batch record. • Review of analytical data (IPC and analysis of finished product) by QC and documentation in batch record. • Review of OOS and deviations and documentation in batch record by the Quality Unit.

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	Positive release of finished product • After batch record review material which conforms to the specification is electronically released by QC. Certificate of Analysis • A Certificate of Analysis is provided with each batch. Documentation • Documentation of production linked records is available for at least 7 years. Validation Validation (completed and on-going) is in place including: • Equipment Qualification • Process Validation • Cleaning Validation • Media Qualification • Analytical Method Validation • Computer Validation (validation of LIMS is completed, critical systems are defined and Validation Master Plan is in place). Control of Noncomforming Product • No reprocessing • No rework • No blending Waste disposal • Waste is treated according to German and EC regulatory requirements for waste management. • Hygiene management of waste is in place.

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Section 4 - Regulatory Information

Compendial compliance and other regulatory status	• **MicroceLac® 100** is a spraydried mixture of 75 parts Lactose Monohydrate (PhEur) and 25 parts Cellulose Microcristalline (PhEur, USP/NF, JP). • The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP.
Drug Master File (DMF) or EDQM Certificate of Suitability or other Master File Availability	• US-Drug Master File number 14052 is current. • No EDQM Certificate of Suitability applied for. • No other Master File submitted.
BSE/TSE and viral safety Information	• BSE/TSE: See www.meggle-pharma.de
Viral safety	• Viral safety information: See www.meggle-pharma.de
Allergens Information	• Gluten: www.meggle-pharma.de
GMO Information	• See www.meggle-pharma.de
Residual Solvents Information	• See www.meggle-pharma.de
Metal catalyst residues	• See www.meggle-pharma.de
Kosher/ Halal	• Certificates may be provided on request as far as available.
Irradiation status	• **MicroceLac® 100** and its ingredients have not been treated with ionising irradiation.
Other concerns, as applicable	• Aflatoxin M1: See www.meggle-pharma.de

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Section 5 - Miscellaneous Product Information

Lot/Batch Numbering System	Lxxyy Azzzz with xx: Year of production yy: Week of production zzzz: MEGGLE article number
Description of Batch Definition	• Continuous production of 1 to 7 days within specification.
Expiration and/or Recommended Re-evaluation Interval	• Shelf life: See www.meggle-pharma.de • Storage conditions: See specification • Recommended reevaluation interval: Not applicable • Retesting: Not applicable
Composition declaration	75% Lactose Monohydrate PhEur + 25% Cellulose Microcristalline PhEur, USP/NF, JP
Common uses	• Pharmaceutical excipient
Nutritional information	Nutritional information according to Directive 90/496/EEC per 100g **MicroceLac® 100**:
Packaging and labeling information e.g. size, types, new/recycled, bulk tankers, tamper evidence	• Packaging material conforms to all relevant legal requirements for packaging material. It is suitable to come into direct contact with the product. • Labeling information: - Name of product - Lot number - Net weight - Expiry date

Energy:	1401 kJ / 332 kcal
Protein:	0.1 g
Carbohydrate:	71 g
- of which sugars:	71 g
Fat:	0 g
- of which saturates:	0 g
Fibre:	24 g
Sodium:	0 g

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	- Recommended storage conditions - Address of MEGGLE - Identification mark (DE-BY 111-EG) • Sizes and types: See www.meggle-pharma.de • Packaging material is specified. • Packaging is new. Packaging is not reused. • Packaging has a tamper proof closure.
MSDS	• Material Safety Data Sheet (MSDS) can be provided on request.

Section 6 Revision history

Revision	Changes made since the last revision
Revision 01	New document

Section 7 Contact Information

In case of questions or additional information needed please contact the Sales Department of the Business Group Excipients & Technology:

Telephone: 0049 (0)8071 73 476
Fax: 0049 (0)8071 73 320
Email: service.pharma@meggle.de

The special agreements in connection with the supply contract including the general conditions of sales and delivery of MEGGLE are not affected by this EIP, especially with regard to warrantee and liability.

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MEGGLE EIP
Part II

Manufacturing Site Quality Overview

Date of issue: 03.11.2009

	Check			Approval
Date of issue Electronic Signature				03.11.2009 Gabriele Mueller, QA/QM
Date of issue Electronic Signature				03.11.2009 Egmont Pfeifer, Head BG E&T

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MEGGLE EIP

PART II Manufacturing Site Quality Overview

This document is Part II of MEGGLE EIP: Manufacturing Site Quality Overview.

The MEGGLE EIP is based on the "IPEC Excipient Information Package (EIP): Template and User Guide, 2009" (http://www.ipecamericas.org) and consists of the following documents (each with separate revision cycles):

- **Part I : Product Regulatory Datasheet**
  available for the products:
  - Lactose Monohydrate PhEur
  - Cellactose® 80
  - MicroceLac® 100
  - StarLac®
- **Part II: Manufacturing Site Quality Overview**
- **Part III: Site and Supply Chain Security Overview**

For definitions and glossary please go to the "IPEC Excipient Information Package (EIP): Template and User Guide, 2009" (http://www.ipecamericas.org).

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Part II of MEGGLE EIP: Manufacturing Site Quality Overview

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Section 1 - Facility Overview

Site Name, Address	Molkerei MEGGLE Wasserburg GmbH & Co. KG Megglestr. 6-12 83512 Wasserburg Germany Further on referred to as „**MEGGLE**".
Excipients covered by this document	Lactose Monohydrate PhEur for oral application: Sieved: **PrismaLac 40, CapsuLac 60, Sachelac 80, SpheroLac 100** Milled : **GranuLac 70, GranuLac 140, GranuLac 200, GranuLac 230, SorboLac 400** Agglomerated : **Tablettose 70, Tablettose 80, Tablettose 100** Spray dried : **FlowLac 90, FlowLac 100** Further on referred to as "**Lactose Monohydrate PhEur**".

	Coprocessed excipients for oral application: **Cellactose 80** — Cellactose 80 is a spraydried mixture of 75 parts Lactose Monohydrate (PhEur) and 25 parts Cellulose Powder (PhEur, USP/NF). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. **MicroceLac 100** — MicroceLac 100 is a spraydried mixture of 75 parts Lactose Monohydrate (PhEur) and 25 parts Cellulose Microcristalline (PhEur, USP/NF, JP). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. **StarLac** — StarLac is a spraydried mixture of 85 parts Lactose Monohydrate (PhEur) and 15 parts white native Maize Starch (PhEur, USP/NF). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. Further on referred to as "**coprocessed excipients**".
Corporate Ownership (if different from site identified in Scope)	• Not applicable
Customer audit policy	• MEGGLE welcomes announced customer audits. For contact information see Section 6 "Contact information" at the end of this document.
General Site Information: history, size, shift	• History: Molkerei MEGGLE Wasserburg was founded in 1887 as a small dairy in Wasserburg near Munich. The company has become a global player and is one of the biggest and

operations, number of employees	best-known producers of dairy in Europe. • Size: 220 000m² • 4 shifts. The production runs 365 days per year. Employees: • Total: About 850 • In production of pharmaceutical excipients: About 100 • In Quality Unit: About 30 • In R&D for pharmaceutical excipients: About 5 • In Sales of pharmaceutical excipients: About 15
Site activities conducted (e.g. packaging, testing, R&D)	• Quality Management • Sales Consumer Products • Marketing and Sales Functional Products including Business Group Excipients & Technology (Sales, R&D, Application Technology) • Production and Technology (Production including packaging, Quality Unit, Supply Chain, Engineering, Industrial Performance, Purchase) • Finance, Controlling and IT • Human Resources, General Administration and Public Relations • Raw Materials Procurement
Primary applications of products produced at this site (pharmaceutical, food, cosmetic, etc)	• Food: Butter, butter preparations and dairy ingredients for food industry • Pharmaceutical excipients: Mainly **Lactose Monohydrate PhEur** and **coprocessed excipients** based on Lactose Monohydrate PhEur. • Feed: Mainly delactosed whey powder
Facility production of antibiotics, steroids or hormone type products	• There is no facility production of antibiotics, steroids or hormone type products. • The plant is authorized according to Hygiene Regulation (EC) No. 853/2004 for the production of dairy products with identification mark DE-BY 111-EG.
Organizational chart (including responsibility for product release)	• Organizational charts are installed and version controlled. They may be provided on request. • Quality Unit consists of QM (Quality Management), QC (Quality Control) chemical/physical, QC microbiological, Quality System, Validation and Regulatory Affairs. QC is responsible for product release.

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Use, scope and control of subcontractors	• There are no subcontractors regarding production. **Lactose Monohydrate PhEur** and **coprocessed excipients** covered by this EIP are produced at MEGGLE. • For external analyses subcontractors (external laboratories) are used. The external laboratories are qualified according to MEGGLE QM System.

Section 2 - Compliance Evidence

ISO registration number and registrar certificates	• All activities of MEGGLE are covered by the certification of ISO 9001 and ISO 14001. • Certificates: See www.meggle-pharma.de • First certification according to ISO 9001 was in 1994. • First certification according to ISO 14000 was in 2001.
GMP Inspections by Competent Authorities (Regulatory Agencies) including outcome	• MEGGLE is liable to the permanent supervision of the Official German Veterinary Authority according to Regulation (EC) No. 853/2004 with identification mark DE-BY 111-EG.
General GMP statements	• GMP according to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients is installed. • MEGGLE GMP statement: See www.meggle-pharma.de
Other certifications or external audit programs	• Not applicable for **Lactose Monohydrate PhEur** and **coprocessed excipients**.

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Section 3 - IPEC-PQG GMP Compliance Details

The Site Molkerei MEGGLE Wasserburg GmbH & Co. KG (further on referred to as „MEGGLE") is in compliance with the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. Parenthetical references are from the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.

➢ Quality Management Systems-Excipient Quality Systems (4)

General Requirements (4.1)	• MEGGLE is in compliance with the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. MEGGLE GMP statement: See www.meggle-pharma.de • Quality Management processes are identified.
Documentation Requirements (4.2)	
General (4.2.1)	• Documents and data which relate to the requirements of the QM-System are controlled.
Quality Manual (4.2.2)	• Quality Manual is installed. • The Quality Manual describes the QM-System, the quality policy and the commitment to applying the quality management standards of the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. • The Quality Manual includes the scope of the quality management system, references to supporting procedures and a description of the interaction between quality management processes.
Control of Documents (4.2.3)	• Procedures for the identification, collection, indexing, filing, storage, maintenance and disposition of controlled documents (including external documents that are part of the QM-System) are established. • Procedures used in the manufacture are documented, implemented and maintained. There are formal controls relating to procedure approval, revision and distribution. The use of the current version is controlled. • Documents and subsequent changes are reviewed and approved by designated qualified personnel before issuance

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	to the appropriate areas, as identified in the documents. • Documents that impact product quality are approved by the quality unit.
Control of Records (4.2.4)	• Procedures for the identification, collection, indexing, filing, storage, maintenance and disposition of records are established. • Records are maintained, legible and identifiable with the product involved. • Entries in records are clear, indelible, signed and dated. • Records are kept for a defined period.
Change Control (4.3)	• Change Control according to IPEC-Americas Significant Change Guide for Bulk Pharmaceutical Excipients is installed. • The Change Control procedure includes an appropriate evaluation of customers' and authorities' information about the change. • The Quality Unit has the responsibility and authority for the final approval of changes.

➢ Management Responsibility (5)

Management Commitment (5.1)	• Top management is engaged and responsible for realisation of customer satisfaction, compliance with the installed standards and legal requirements.
Customer Focus (5.2)	• Top management is responsible to ensure that customer requirements are determined and met. • Customer-Audits to review the QM-System, manufacturing processes, buildings and facilities are welcome.
Quality Policy (5.3)	• Top management is committed to the quality policy and ensures the implementation within the company.
Planning (5.4)	
Quality Objectives (5.4.1)	• Top management sets objectives for adherence to GMP to ensure that the excipients manufacturer maintains and improves its performance.

Quality Management System Planning (5.4.2)	• Top management identifies resource requirements and provides adequate resources to ensure conformance to the provision of IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.
Responsibility, Authority and Communication (5.5)	
Responsibility and Authority (5.5.1)	• Top management clearly defines and communicates the responsibilities and authorities within the organisation. • Job descriptions are installed. • Organisation charts are installed. • Quality Unit is independent from production. • Responsibilities are defined and controlled: - to ensure that quality-critical activities are undertaken as defined - to approve suppliers - to approve or reject raw materials and finished products - to ensure that there is a review of production records - to participate in reviewing and authorising changes, specifications, procedures and test methods - to participate in investigating failures and complaints - develop and implement a self inspection programme.
Management Representative (5.5.2)	• Head of Quality Unit is defined. • Head of Unit periodically reports to top management on conformance to the QM-System, including changing customer and regulatory requirements.
Internal Communication (5.5.3)	• Appropriate internal communication to communicate GMP and regulatory requirements, quality policies, quality objectives and procedures is established. • Top management is notified of quality-critical situations.
Management Review (5.6)	
General (5.6.1)	• Review is installed.

Review Input (5.6.2)	• QM-Review includes: - results of internal and external audits - customer feedback of the company - product conformity and process performance - action items from the previous QM-Review - Customer complaints - Corrective and preventive actions - Changes
Review Output (5.6.3)	• QM-Review identifies the resources needed and opportunities for improvement. • A record of actions recommended and taken is made.

➢ **Resource Management (6)**

Provision of Resources (6.1)	• There are sufficient qualified personnel. • There are sufficient resources (buildings, equipment, materials).
Human Resources (6.2)	
General (6.2.1)	• Personnel have appropriate combination of education, training and experience. • Competence, awareness and training of personnel is based on competent specifications of skills and know-how. Corresponding sourcing and mentorship for start-up of personnel are installed.
Competence, Awareness and Training (6.2.2)	• Procedures for identifying training needs and providing the necessary training to personnel are established. • A training schedule is established. • Records of training are maintained. • GMP training is conducted to ensure that employees remain familiar with applicable GMP principles. • Continued personal hygiene training is established so that personnel understand the precautions necessary to prevent contamination of excipients.
Personnel Hygiene (6.2.3)	• To protect the products from contamination protective clothing and head coverings are worn.

	• Contamination with loose items is controlled. • Only authorised personnel enters those buildings designed as limited access areas. • Personnel practices good sanitation and health habits. • Any person shown to have an apparent illness or open lesions that may adversely affect the safety or quality of the products is excluded from direct contact with raw materials and the products. • Personnel is instructed to report to supervisory personnel any health conditions that may have an adverse effect on excipients.
Infrastructure (6.3)	
Buildings and Facilities (6.3.1)	• Buildings and facilities used for production, packaging, testing and storage are in a good state of repair and are of suitable size, construction and location to facilitate cleaning, maintenance and correct operation.
Equipment (6.3.2)	• Equipment used for production, packaging, testing and storage is in a good state of repair and is of suitable size, construction and location to facilitate cleaning, maintenance and correct operation. • Equipment qualification for the GMP relevant process is in place.
Equipment Construction (6.3.2.1)	• Only closed production equipment is used. • Process equipment is constructed so that contact surfaces are not reactive, additive or absorptive and thus not alter the quality of the excipients. • Lubricants are suitable for use in food applications and are controlled according to the HACCP concept. • Coolants do not come into contact with raw materials, packaging materials, intermediates or finished excipients.
Equipment Maintenance (6.3.2.2)	• Documented procedures for quality-critical equipment maintenance are established and followed. • There are records of use and maintenance of quality-critical equipment.
Computer Systems (6.3.2.3)	• GMP critical computer systems have sufficient controls to prevent unauthorized access to computer software, hardware or data.

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	• Back-ups and archival systems are in place. • Computer validation according to Validation Master Plan.
Utilities (6.3.3)	• Utilities (water, compressed air, steam) used in production that could have an impact on excipients quality have been assessed and appropriate action has been taken to control the risk of contamination and cross-contamination. Media qualification is in place.
Water (6.3.4)	• Drinking water according to Directive (EC) No. 98/83 or demineralised water made from drinking water according to Directive (EC) No. 98/83 is used. • Water that comes into contact with the excipients is supplied under continuous positive pressure or other means of preventing back flow. • Analytical verification of water quality is in place.
Work Environment (6.4)	• The production is performed in closed equipment so that there is no exposure of the product during production.
Air Handling (6.4.1)	• Air used in production is filtered. • In packaging areas air handling systems are installed to provide protection to the excipient. • Qualification of GMP relevant equipment is part of equipment qualification.
Controlled Environment (6.4.2)	• Not applicable
Cleaning and Sanitary Conditions (6.4.3)	• Buildings are maintained in appropriately clean and sanitary conditions. • Cleaning of buildings and facilities is installed. • Cleaning is documented. • Maintenance of buildings is installed. • Waste is segregated and disposed of in a timely and appropriate manner.
Pest Control (6.4.4)	• Pest control is installed comprising rodents, birds and insects (crawling and flying).
Lighting (6.4.5)	• Adequate lighting for cleaning, maintenance and proper

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	operation is provided.
Drainage (6.4.6)	• Drains are of adequate size and where connected directly to a sewer, back-siphoning is prevented.
Washing and Toilet Facilities (6.4.7)	• Adequate personal washing facilities are provided including hot and cold water, soap and single service towels. • Clean toilet facilities separated but easily accessible to working areas are provided. • Adequate facilities for showering and changing clothes are provided.

➢ **Product Realisation (7)**

Planning of Product Realisation (7.1)	• Processes and controls needed for product manufacture are planed and developed. Key aspects are: - documented testing programs that include appropriate specifications, sampling plans, test and release procedures - generation and maintenance of records (see also 4.2.4) that provide evidence that these plans have been realised as indented and that enable traceability to be demonstrated (see also 7.5.3.1) - provision of resources to implement these plans - environmental and hygiene control programs to minimise contamination.
Customer-Related Processes (7.2)	
Determination of Requirements Related to the Product (7.2.1)	• Excipient quality and delivery requirements of the customer are determined.
Review of Requirements Related to the Product (7.2.2)	• MEGGLE and the customer mutually agree upon the requirements identified in 7.2.1 before supply commences. MEGGLE has the facility and process capability to meet consistently the mutually agreed specifications. Where the requirements determined in 7.2.1 are changed this review

	should be repeated before supply commences.
Customer Communication (7.2.3)	• Accurate and pertinent communication to the customer is provided. • Customer enquiries, contracts and order handling requirements are replied to. • Customer complaints are documented. • Customers are notified of significant changes (see also 4.3).
Design and Development (7.3)	• Design and development activities follow ISO 9001.
Purchasing (7.4)	
Purchasing Process (7.4.1)	• Materials are purchased against agreed specifications from approved suppliers. • There is a system for selecting and approving suppliers of materials. • Audits of supplier's manufacturing facilities are performed according to installed audit plan.
Purchasing Information (7.4.2)	• Purchasing agreements describe the material ordered.
Verification of the Purchased Product (7.4.3)	• There are procedures for the release of raw materials. • Upon receipt, raw materials are inspected according to defined requirements and are not used prior to acceptance. • Sampling activities are conducted in accordance with a defined sampling method and using procedures designed to prevent contamination and cross-contamination. • Bulk deliveries require a certificate of cleaning to have additional controls to assure material purity and freedom from contamination. • Procedures, activities and results are documented.
Production and Service Provision (7.5)	
Control of Production and	

Service Provision (7.5.1)	
Production Instructions and Records (7.5.1.1)	• Production instructions are installed and are available in the production area. • Records are available for each batch of excipient produced and include complete information relating to the production and control of each batch. • The batch is defined. • Records are readily retrievable. • Records include - date/time - identification of persons performing and directly supervising or checking operations or control parameter - identification of major equipment and lines used - material inputs to enable traceability, for example batch number and quantities of raw materials added - in-process and laboratory control results - the quantity produced - line clearance - description of excipients product containers and closures - description of sampling performed - deviations and their investigations.
Equipment Cleaning (7.5.1.2)	• Cleaning validation is in place. • Cleaning procedures are designed, justified and evidence of their effectiveness is provided. • Cleaning procedures are documented. • Cleaning procedures contain sufficient detail to allow operators to clean each type of equipment in a reproducible way and effective manner. • There are records that the cleaning procedures have been followed. • The frequency of equipment cleaning is determined and justified.
Recovery of Solvents, Mother Liquors and Second Crop Crystallisations (7.5.1.3)	• No organic solvents used. • The reuse of mother liquors and filtrates containing recoverable amounts of excipient or intermediates is documented to enable traceability.

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In-process Blending or Mixing (7.5.1.4)	• Not applicable
In-process Control (7.5.1.5)	• In-process inspection and testing is performed at defined locations and times. • Sampling methods are documented and ensure that the sample is representative and clearly labelled. • Results of the in-process tests are recorded and conform to established process parameters or acceptable tolerances. • Work instructions define procedures how to utilise the inspection and test data to control the process. There are defined actions to be taken when the results are outside specified limits.
Packaging and Labelling (7.5.1.6)	• During packaging and labelling quality and purity of the excipient is protected and mix-ups are prevented. • Procedures are installed that ensure that where applicable correct labels are printed and issued. • Where excipients are labelled on the packaging line in pre-printed bags there is documentation of the system used to satisfy the intent of above procedures.
Records of Equipment Use (7.5.1.7)	• Records of quality-critical equipment use are retained. These records allow the sequence of cleaning, maintenance and production activities to be determined.
Validation of Processes for Production and Service Provision (7.5.2)	• Validation Mater Plan is installed.
Identification and Traceability (7.5.3)	
Traceability (7.5.3.1)	• Quality-critical items, for example raw materials, packaging materials, intermediates and finished excipients are clearly identified and traceable through records. These records allow traceability upstream and downstream.
Inspection and Test Status (7.5.3.2)	• There is a system to identify the inspection status of quality-critical items including raw materials, intermediates and

	finished products.
Labelling (7.5.3.3)	• National and international regulatory requirements are met. • As a minimum the label/labelling includes: - name of the excipient - excipient producer's name - batch number from which the complete batch history can be determined.
Customer Property (7.5.4)	• Customer-supplied materials: Not applicable
Preservation of the Product (7.5.5)	
Handling, Storage and Preservation (7.5.5.1)	• Excipients, intermediates and raw materials are handled and stored under appropriate conditions so that their identity, quality and purity are not affected.
Packaging Systems (7.5.5.2)	• The excipient package system includes the following features: - documented specifications - tamper-evident seals - adequate protection against deterioration or contamination of the excipient during transportation and recommended storage - no interaction with or contamination of the excipient. • Containers are not reused.
Delivery and Distribution (7.5.5.3)	• Distribution records of excipients shipments are kept. These records identify, by excipient batch, where and to whom the excipient was shipped, the amount shipped and the date of shipment. • Excipients are only supplied within their expiry period.
Control of Measuring and Monitoring Devices (7.6)	• Measuring and test equipment identified as being quality-critical are calibrated and maintained. This includes in-process instruments as well as test equipment used in the laboratory. • The control program includes the calibration of instruments and equipment at suitable intervals in accordance with an established documented program. This program includes specific directions, schedules, limits for accuracy and

	precision and provisions for remedial action in the event that accuracy and/or precision limits are not met. • Calibration standards are traceable to recognised national or compendial standards as appropriate. • Instruments and equipment not meeting established specifications are not used and an investigation is conducted to determine the validity of the previous results since the last successful calibration. • The current calibration status of quality-critical equipment is known and verifiable to users.

➢ **Measurement, Analysis and Improvement (8)**

General (8.1)	• Improvement is considered as a major driving force.
Monitoring and Measurements (8.2)	
Customer Satisfaction (8.2.1)	• Customer satisfaction is assessed, including measurements of - customer complaints, - returns of excipients, - customer audits and - customer feedback.
Internal Audit (8.2.2)	• A comprehensive system of planned and documented internal quality audits is carried out. The internal audits determine whether quality activities comply with planned arrangements and the effectiveness of the quality management system. • Internal audits and follow-up actions are carried out in accordance with documented procedures. • Audit results are documented.
Monitoring and Measurement of Processes (8.2.3)	• MEGGLE identifies the tests and measurements necessary to adequately control manufacturing and quality management system processes. Where critical to excipient quality, techniques that are used to verify that the processes are under control are established. • Corrective actions are taken to ensure the excipients meet requirements when deviations from planned results occur.

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	• Periodic reviews of key indicators such as process quality attributes and process failures are conducted to assess the need for improvements.
Monitoring and Measurement of Product (8.2.4)	• Test methods and procedures are established to ensure the product consistently meets specifications. • Analytical methods used are compendial or are validated. • Compliance with applicable general chapters and notices are given.
Laboratory Controls (8.2.4.1)	• Laboratory controls include: - a description of the sample received for testing together with the material name, batch number or other distinctive code and date the sample was taken - a statement referencing each test method used - a record of raw data secured during each test including graphs, chromatograms, charts and spectra from laboratory instrumentation, identified to show the specific batch tested - a record of calculations performed in connection with the test - test results and how they compare with established specifications - a record of the person who performed each test. • There is a documented procedure for the preparation of laboratory reagents and solutions. • Purchase solutions are labelled with the proper name, concentration and expiry date. • Records are maintained for the preparation of solutions including the name of the solution, date of preparation and quantities of material used. • Volumetric solutions are standardised and records of the standardisation are maintained. • Primary reference reagents and standards are appropriately stored and are not tested upon receipt provided that a certificate of analysis from the supplier is available. Secondary reference standards are appropriately prepared, identified, tested, approved and stored. There is a documented procedure for the qualification of secondary reference standards. The re-evaluation period is defined for secondary reference standards and each batch is periodically requalified in accordance with a documented protocol or procedure.
Finished Excipient	• Finished excipient testing is performed on each batch to

Testing and Release (8.2.4.2)	ensure that the excipients conform to documented specification. • There is a procedure to ensure that appropriate production documentation, in addition to the test results is evaluated prior to release of the finished excipients. • The quality unit is responsible for the release of the finished excipient.
Out-of-Specification Test Results (8.2.4.3)	• Out-of-specification (OOS) test results are investigated and documented according to a documented procedure. • Retest sample results are only used to replace the original test result if it is demonstrated that the original result is erroneous based on a documented investigation.
Retained Samples (8.2.4.4)	• A representative sample of each batch of the excipient is retained. • The retention period is the shelf life + 1 year. • The retained samples are stored and maintained in such a manner that they are readily retrievable in facilities that provide a suitable environment. • The sample size is at least twice the amount required to perform complete specification testing.
Certificate of Analysis (8.2.4.5)	• MEGGLE provides a certificate of analysis to the required specification for each batch of excipient.
Impurities (8.2.4.6)	• MEGGLE identified and set appropriate limits for impurities. • Production processes are adequately controlled so that the impurities do not exceed such established limits. • Organic solvents are not used.
Stability (8.2.4.7)	• Stability testing according to ICH guidelines has been performed. • On-going stability testing is installed. • The results of such stability testing are used to determining appropriate storage conditions and expiry dates. • The testing program includes the following: - the number of batches and test intervals - storage conditions for samples retained for testing - storage of the excipients in containers that simulate the market container, where possible.
Expiry/Retest Periods (8.2.4.8)	• An expiry period is assigned to each excipient and communicated to the customer.

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Control of Nonconforming Product (8.3)	• Raw material, intermediate or finished excipients found not to meet its specification are clearly identified and controlled to prevent inadvertent use or release for sale. • A record of nonconforming product is maintained. • Incidences of non-conformance are investigated to identify the cause. The investigation is documented and action is taken to prevent recurrence. • There is a documented procedure defining how the retrieval of a nonconforming product from distribution is conducted and recorded. • Procedures exist for the evaluation and subsequent handling of nonconforming products.
Reprocessing (8.3.1)	• **Lactose Monohydrate PhEur:** Reprocessing according to defined procedures. • **Coprocessed excipients:** No reprocessing.
Reworking (8.3.2)	• Not applicable. No reworking.
Returned Excipients (8.3.3)	• Returned excipients are identified and quarantined until the quality unit has completed an evaluation of their quality. • There are procedures for handling of returned excipients in place. • Records for returned products are maintained and include the name of the excipient and the batch number, reason for return, quantity returned and ultimate disposition of the returned excipient.
Analysis of Data (8.4)	• Annual quality review is performed comprising customer complaints, product reviews, internal and customer audits. The analysis of such data is used as part of the review (see also 5.6). • A periodic review of key indicators such as product quality attributes, customer complaints and product nonconformities are conducted to assess the need for improvements and the need for revalidation and requalification.
Improvement (8.5)	
Continual Improvement	• MEGGLE takes proactive measures to continuously improve manufacturing and quality management system processes.

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(8.5.1)	
Corrective Action (8.5.2)	• MEGGLE has established, documented and maintained procedures for - determining the root causes of nonconformities - implementing corrective actions - implementing and recording changes in procedures resulting from corrective actions.
Preventive Action (8.5.3)	• MEGGLE has established, documented and maintained procedures for - initiating preventive actions to deal with problems at a level corresponding to the risks - implementing and recording changes in procedures resulting from the preventive action.

Section 4 - Miscellaneous Site Information

HACCP	• HACCP according to the legal requirements is installed.
Insurance	• Liability Insurance covers general liability (premises/operations and products/completed operations) for bodily injury and property damage. Certificate of Insurance may be provided on request.

Section 5 - Revision History

Revision	Changes made since the last revision
Revision 01	New document

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Section 6 - Contact Information

In case of questions or additional information needed please contact the Sales Department of the Business Group Excipients & Technology:

Telephone: 0049 (0)8071 73 476
Fax: 0049 (0)8071 73 320
Email: service.pharma@meggle.de

The special agreements in connection with the supply contract including the general conditions of sales and delivery of MEGGLE are not affected by this EIP, especially with regard to warrantee and liability.

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MEGGLE EIP

Part III

Site and Supply Chain Security Overview

Date of issue: 25.11.2010

	Check			Approval
Date of issue Electronic Signature				25.11.2010 Gabriele Mueller, QA/QM
Date of issue Electronic Signature				25.11.2010 Egmont Pfeifer, Head BG E&T

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MEGGLE EIP

PART III Site and Supply Chain Security Overview

MEGGLE

This document is Part III of **MEGGLE** EIP: Site and Supply Chain Security Overview.

The **MEGGLE** EIP is based on the "IPEC Excipient Information Package (EIP): Template and User Guide, 2009" (http://www.ipecamericas.org) and consists of the following documents (each with separate revision cycles):

- **Part I : Product Regulatory Datasheet**
  available for the products:
  - Lactose Monohydrate PhEur
  - Cellactose® 80
  - MicroceLac® 100
  - StarLac®
- **Part II: Manufacturing Site Quality Overview**
- **Part III: Site and Supply Chain Security Overview**

For definitions and glossary please go to the "IPEC Excipient Information Package (EIP): Template and User Guide, 2009" (http://www.ipecamericas.org).

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MEGGLE EIP
PART III Site and Supply Chain Security Overview

MEGGLE

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MEGGLE EIP
PART III Site and Supply Chain Security Overview

MEGGLE

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Section 1 - Scope

Site Name and Address of production and release site	Molkerei MEGGLE Wasserburg GmbH & Co. KG Megglestr. 6-12 83512 Wasserburg Germany Further on referred to as „**MEGGLE**".
Description of the Supply Chain Scope	Description of the Supply Chain: • **MEGGLE** produces products for global supply. • Business relationships exist between **MEGGLE** and the customers directly or there is an authorized Distributor in between, depending on the country of destination and the amount of product to be delivered. Brokers are not used. • The transport is organized by **MEGGLE**, the Distributor or the Customer. **MEGGLE** authorized Distributors: • **MEGGLE** authorized Distributors are only handling originally closed **MEGGLE** products. There is no repacking and no relabelling performed by the Distributors. The Distributors do no sampling, testing or resting without the agreement of **MEGGLE** (in exceptional cases). The original **MEGGLE** Certificate of Analysis is forwarded. All **MEGGLE** authorized Distributors are aware that they are handling excipients for pharmaceutical applications. • For an overview over the authorized Distributors please go to www.meggle-pharma.de. This EIP • This EIP describes the system installed at **MEGGLE Site Wasserburg** for the Site and Supply Chain security. • This EIP also describes the GDP system which **MEGGLE** did install with its authorized Distributors. The responsibilities for the activities performed by the authorized Distributors in the Supply Chain remain with the authorized Distributors. • This EIP does not describe the activities performed by the customers in the Supply Chain. The responsibilities for the activities performed by the customers in the Supply Chain remain with the customers.

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Excipients covered by this document	Lactose Monohydrate PhEur:

Sieved:	**PrismaLac® 40** **CapsuLac® 60** **Sachelac® 80** **SpheroLac® 100** **InhaLac® 70** **InhaLac ®120** **InhaLac® 130**
Milled :	**GranuLac® 70** **GranuLac® 140** **GranuLac® 200** **GranuLac® 230** **SorboLac® 400**
Agglomerated :	**Tablettose® 70** **Tablettose® 80** **Tablettose® 100**
Spray dried :	**FlowLac® 90** **FlowLac® 100**

Further on referred to as "**Lactose Monohydrate PhEur**".

	Coprocessed excipients: **Cellactose® 80** — Cellactose 80 is a spraydried mixture of 75 parts Lactose Monohydrate (PhEur) and 25 parts Cellulose Powder (PhEur, USP/NF, JP). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. **MicroceLac® 100** — MicroceLac 100 is a spraydried mixture of 75 parts Lactose Monohydrate (PhEur) and 25 parts Cellulose Microcristalline (PhEur, USP/NF, JP). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. **StarLac®** — StarLac is a spraydried mixture of 85 parts Lactose Monohydrate (PhEur) and 15 parts white native Maize Starch (PhEur, USP/NF). The monograph „Lactose Monohydrate" is harmonized between PhEur, USP/NF and JP. Further on referred to as "**Coprocessed Excipients**".
Corporate Ownership (if different from site identified in Scope)	Not applicable

MEGGLE EIP
PART III Site and Supply Chain Security Overview

Section 2 - Supply Chain Security

Evaluation of carriers	• Carriers engaged by **MEGGLE** are obliged to sign rules for the transport ensuring that the quality of the excipients is not changed and that legal obligations are met during transport.
Tamper evident packaging	• Packaging materials of **Lactose Monohydrate Ph.Eur.** and **Coprocessed Excipients** (bags, big bags, cartons) have a tamper evident closure.
Distributors / Brokers:	• **MEGGLE** works with Distributors as described in Section 1 • **MEGGLE** does not work with brokers. GDP: • **MEGGLE** did install a GDP system with its approved Distributors which is contractual laid down in the following elements: 1. Distribution Agreement between **MEGGLE** and the Distributors with **MEGGLE** GDP Requirements in the Annex. 2. Quality Agreement between **MEGGLE** and the Distributors based on the IPEC Quality Agreement Guide. 3. Audits performed by **MEGGLE** at the Distributors according to the IPEC Good Distribution Practices Audit Guide for Pharmaceutical Excipients. • **MEGGLE** GDP requirements are based on the WHO Good Trade and Distribution practices/GTDP) for pharmaceutical starting materials and IPEC Good Distribution Guide (GDP) for Pharmaceutical Excipients. • For details of **MEGGLE** GDP requirements installed at all Distributors please see Annex 1.

Section 3 - Security Information

Security Plan Scope • Roles and Responsibilities • Policies & Procedures • Training • Data and computer system protection	• **MEGGLE** works in accordance with the typical standards for dairy enterprises in Germany and Europe. • **MEGGLE** Data and Computer systems are protected. SOPs regarding protection against virus attacks, access to the computer system (including user identification and pass words) and data security (including archiving and audit trails) are installed.
Site access control (e.g. security fencing, visitor registration, employee badges, employee training, vehicular access, camera monitoring)	Site access control is installed at **MEGGLE**, including: • security fencing • visitor registration • employee access cards • employee training • vehicular access control and • camera monitoring
Personnel security • Pre-employment background checks • Background checks on temporary and contract personnel • Termination of employees or contractors and preventing subsequent access to the site and computer systems	• Pre-employment background checks such as: - checks at public registration offices - checks at public prosecution departments - checks at the police - checks at driving licence departments - checks at psychologists are not performed by **MEGGLE**. • After termination of the employer-employee relationship access to the **MEGGLE** production site and the computer system is denied.

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Section 4 - Safety & Environmental Information

Description of Documented Health and Safety Program	• All applicable legal requirements of Germany and Europe referring to the health and the safety of the employees are obeyed. Please also see the **MEGGLE** Code of Conduct in Section 5.
Registrations to ISO 14001, OHSAS 18001	• **MEGGLE** is certified according to ISO 14001 since 2001.
Description of Documented Emergency Response Plan	• Documented Emergency Response Plans are installed. Close contact the local fire department.

Section 5 - Miscellaneous Product Information

Corporate Social responsibility programs	**MEGGLE Code of conduct:** 1) **Compliance with laws** The state and society shall provide the framework conditions of our entrepreneurial activity. We undertake to comply with all laws applicable to us, including laws relating to employment, discrimination, and the health and safety of our employees. Furthermore, we undertake to comply with all effective internal company agreements. 2) **Freedom of assembly and right of collective bargaining** We shall grant our employees the right of freedom of assembly and organisation in trade unions and associations (collective bargaining). 3) **Ban on discrimination** We shall not accept any form of discrimination, be it on the grounds of • Gender • Age

	• Religious denomination • Race • Social origin • Disability • Ethnic or national origin • Nationality • Membership in trade unions • Political affiliation • Sexual orientation 4) **Treatment of employees** We shall not accept any form of harassment. We equally condemn mental and physical punishment as well as other forms of mistreatment. 5) **Salaries and wages** We shall guarantee that the wages/salaries we pay are in line with the industry standard. We shall ensure that the level of wages/salaries paid covers our employees' cost of living (elementary needs). We shall not make any illegal or unauthorised wage deductions. 6) **Working time** Working hours and holiday entitlement shall be governed by collective agreement. Holiday entitlement for employees under 60 years of age currently amounts to 30 working days per year. Employees over 60 years of age shall have an annual holiday entitlement of 42 working days. We shall guarantee that the maximum weekly working time will not exceed 40 hours and that the maximum overtime worked per week will not exceed 12 hours. Any overtime performed by our employees shall be on a strictly voluntary basis and dealt with in accordance with the provisions of the collective agreement. 7) **Safety in the workplace** We stand by our responsibility for the health and safety of our staff in the workplace. We have introduced clear rules and measures, which contribute to health and

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	safety in the workplace. We shall apply and comply with these rules and measures. Our staff undergoes constant training regarding work safety. Furthermore, we see it as the task of the employer to offer general measures for the promotion of health in the workplace to our employees. No practices or conditions which violate human rights shall be applied to work stations within the company. 8) **Ban on child labour** We undertake not to use child labour and not to employ young people under the age of 15 years. 9) **Working conditions** We shall oppose any form of exploitation of employees, as well as working conditions similar to slavery or constituting a health hazard. 10) **Ban on forced labour** We shall oppose any form of forced labour. We equally condemn any form of convict labour which violates basic human rights.
Business continuity Plans	• A Disaster Recovery plan is installed for **Lactose Monohydrate Ph.Eur.** and **Coprocessed Excipients** and may be provided on request.

Section 6 - Revision History

Revision	Changes made since the last revision
Revision 01	New document

Section 7 - Contact Information

In case of questions or additional information needed please contact the Sales Department of the Business Group Excipients & Technology:

Telephone: 0049 (0)8071 73 476
Fax: 0049 (0)8071 73 320
Email: service.pharma@meggle.de

The special agreements in connection with the supply contract including the general conditions of sales and delivery of **MEGGLE** are not affected by this EIP, especially with regard to warrantee and liability.

ANNEX 1:
Details of MEGGLE GDP requirements installed at all MEGGLE authorized Distributors:

1. Prerequisites:

- Warehousing, trading and reselling and all other handling of **MEGGLE** products are limited to originally packed excipients.
- Repacking and relabelling under **MEGGLE** brand are generally excluded activities in the distribution chain.
- Sampling, testing or retesting are generally excluded activities in the distribution chain. Exceptions have to be agreed with **MEGGLE**.
- All Distributors are aware that they are handling excipients for pharmaceutical applications and that excipients may influence patients' safety.

2. Quality Management

- Parties involved in the excipient Supply Chain have established an adequate Quality Management System to manage the quality of their products and services, in order to maintain the original quality of the excipients. As an essential prerequisite the top management of the Distributors is responsible that the **MEGGLE** GDP Requirements are realized.

3. Organization and Personnel

- All personnel are aware of the principles of the **MEGGLE** GDP requirements.

4. Premises

- Premises are located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, mix-ups, build-up of dust or dirt, strong smell and, in general, any adverse effect on the quality of materials.
- Measures are in place to prevent unauthorized persons from entering the premises after business hours.
- Premises are designed and equipped so as to afford maximum protection against the entry of insects, rodents or other animals.
- Suitable supporting facilities and utilities (such as air control, lighting and ventilation) are in place and appropriate to the activities performed.

5. Warehousing and Storage

- Procedures are in place, especially but not limited to:
  - Receipt: visual inspection of the pallet integrity, confirmation of material identity from the pallet label against documentation, evidence of infestation;
  - Storage: cleanliness of excipient storage area, accuracy of the inventory locator system;
  - Dispatch: truck cleanliness, tracking records, verification of correct material by matching excipient label against dispatch documentation, cleanliness of containers, and transport equipment.
- Excipients are stored in a manner to protect their quality as well as their packaging and labelling. The facility is organized in a manner to facilitate selection of designated materials. Excipients are stored in conformance with safety requirements.
- Protection from adverse environmental conditions is considered as a minimum requirement.
- Rejected, recalled and returned material, including those with damaged packaging, are clearly identifyable. Segregation is achieved through physical or computer control with appropriate systems in place.
- Highly active materials, narcotics, other dangerous drugs and substances presenting special risks of abuse, fire or explosion are stored in safe, dedicated and secure areas. In addition international conventions and national legislation apply.
- Spillages are cleaned as soon as possible to prevent possible cross contamination and hazard.
- Provisions are made for the proper and safe storage of waste materials awaiting disposal.
- Toxic substances and flammable materials are stored in suitably designed, separate, closed containers in enclosed areas, taking into account the relevant national legislation.
- A system is in place to ensure that those materials due to expire first are sold or distributed first (Earliest Expiry/First Out (EEFO).
- There are records to show when inspections were made including observations of the findings for vermin and all pest control activities. Materials used for control of vermin do not adversely affect the excipients.

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6. Documentation

- A Distributor does not change the original title and data of the Certificate of Analysis (COA) or other quality documents. The original **MEGGLE** documentation is used.
- Before any material is sold or distributed, the Distributor ensures that the COAs are available. For each shipment the COA is forwarded to the pharmaceutical product manufacturer.
- Traceability is installed upstream and downstream and is available on reasonable request.
- Mechanisms exist to allow the transfer of information, including the transfer of quality or regulatory information between a manufacturer and a customer and of information to the regulatory authority upon request (e.g. Change Control).
- Relevant storage, handling and safety data sheets are available.
- Records are kept and are readily available upon request.

7. Complaints

- Product-related customer complaints and information about possible defects are forwarded to **MEGGLE** without delay.
- Any complaint concerning defects originating in the Supply Chain from the Distributor is recorded and thoroughly investigated to identify the origin or reason for the complaint.

8. Recalls

- There is a system for promptly and effectively recalling materials known or suspected to be defective from the market.
- **MEGGLE** will be informed in the event of a recall.
- All recalled materials are stored secure while their fate is decided.
- In the event of serious or potentially life-threatening situations and in consultation with **MEGGLE** all customers and competent authorities in all countries to which a given material may have been distributed are promptly informed of any intention to recall the material.
- All records are readily available to the person(s) responsible for recalls. These records contain sufficient information on materials supplied to customers (including exported materials).

9. Returned goods

- Returned excipients are identified as such and held pending resolution. Procedures addressing the keeping of the material in quarantine are in place.
- Records of returned products are maintained and include the name of the excipient and the lot number (batch number), reason for the return, quantity returned, date of disposition, and ultimate fate of the returned excipient.
- For material under quarantine the same storage conditions apply as for normal material.

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10. Handling of non-conforming materials

- Non-conforming materials are being prevented from introduction or reintroduction into the market.
- Records covering all activities, including destruction, disposal, return and reclassification, are maintained.
- If reasonable an investigation is performed to establish whether any other batches are also affected. Corrective measures are taken where necessary.
- The disposition of the material, including downgrading to other suitable purposes is decided together with **MEGGLE** and is documented.

11. Dispatch and Transport

- Transport conditions and the equipment to be used are defined according to the characteristics of the products: Under dry and odour free conditions.
- Packaging materials and transportation containers are suitable to prevent damage during transport.
- Steps are taken to prevent unauthorized access to the materials being transported.
- General international requirements regarding safety aspects are observed.

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BASF
The Chemical Company

Safety data sheet

BASF Safety data sheet according to Regulation (EC) No. 1907/2006
Date / Revised: 25.06.2010 Version: 3.2
Product: **Caffeine Anhydrous Granular 0.2/0.7**
(30057315/SDS_GEN_EU/EN)
Date of print 26.06.2010

1. Identification of the substance/mixture and of the company/undertaking

Caffeine Anhydrous Granular 0.2/0.7

Company:
BASF SE
67056 Ludwigshafen
GERMANY
Operating Division Care Chemicals
Telephone: +49 621 60-48434
Telefax number: +49 621 60 66-48434
E-mail address: EM-Masterdata@basf.com

Emergency information:
International emergency number:
Telephone: +49 180 2273-112

2. Hazards Identification

According to REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Label elements and precautionary statement:

Pictogram:

Signal Word:
Warning

Hazard Statement:
Harmful if swallowed.

Precautionary Statements (Prevention):
Do no eat, drink or smoke when using this product. Wash with plenty of water and soap thoroughly after handling.

Call a POISON CENTER or doctor/physician if you feel unwell. IF SWALLOWED: rinse mouth.

Precautionary Statements (Disposal):
Dispose of contents/container to hazardous or special waste collection point.

Classification of the substance and mixture:
Acute toxicity: Cat. 4 (oral)

Other hazards which do not result in classification:
The product is under certain conditions capable of dust explosion.

Possible Hazards (according to Directive 67/548/EWG or 1999/45/EC)

Harmful if swallowed.
The product is under certain conditions capable of dust explosion.

3. Composition/Information on Ingredients

Chemical nature

caffeine

CAS Number: 58-08-2
EC-Number: 200-362-1
INDEX-Number: 613-086-00-5

4. First-Aid Measures

General advice:
Remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air, seek medical attention.

On skin contact:
Wash thoroughly with soap and water.

On contact with eyes:
Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:
Immediately rinse mouth and then drink 200-300 ml of water, seek medical attention.

Note to physician:
Treatment: Treat according to symptoms (decontamination, vital functions), no known specific

5. Fire-Fighting Measures

Suitable extinguishing media:
water spray, dry powder, carbon dioxide, foam

Unsuitable extinguishing media for safety reasons:
water jet

Special protective equipment:
Wear a self-contained breathing apparatus.

Further information:
Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

Personal precautions:
Avoid dust formation. Ensure adequate ventilation. Information regarding personal protective measures see, chapter 8.

Environmental precautions:
Do not discharge into drains/surface waters/groundwater. Discharge into the environment must be avoided.

Methods for cleaning up or taking up:
For small amounts: Pick up with suitable appliance and dispose of.
For large amounts: Pick up with suitable appliance and dispose of.
Dispose of absorbed material in accordance with regulations. Avoid raising dust.

7. Handling and Storage

Handling

Avoid the formation and deposition of dust.

Protection against fire and explosion:
The product is capable of dust explosion. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Storage

Further information on storage conditions: Keep container tightly closed. Protect contents from the effects of light.

8. Exposure Controls/Personal Protection

Personal protective equipment

Respiratory protection:
Breathing protection if breathable aerosols/dust are formed. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2)

Hand protection:
Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other Supplementary note: The specifications are based on tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined through testing.

Eye protection:
Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection:
Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

General safety and hygiene measures:
Wearing of closed work clothing is recommended. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. When using, do not eat, drink or smoke.

9. Physical and Chemical Properties

Form:	powder	
Colour:	white	
Odour:	almost odourless	
pH value:	5.5 - 6.5 (10 g/l, 20 °C)	
pKA:	10.4 (40 °C)	(other)
melting range:	approx. 235 - 239 °C	
Flash point:	not applicable	
Flammability:	not readily ignited	
Ignition temperature:	> 600 °C	(DIN 51794)
Self ignition:	not self-igniting	

Minimum ignition energy:
The product is capable of dust explosion.

Fire promoting properties: not fire-propagating (other)

Vapour pressure: < 0.0000001 hPa (calculated)
(25 °C)
Very low, negligible

Density: 1.23 g/cm3
(18 °C)
Literature data.

Bulk density: approx. 360 kg/m3

Solubility in water:
20 g/l
(20 °C)

Partitioning coefficient n-octanol/water (log Pow): -0.091 (Directive 92/69/EEC, A.8)
(23 °C)

Viscosity, dynamic:
not applicable

Molar mass: 194.19 g/mol

10. Stability and Reactivity

Conditions to avoid:
Avoid dust formation. See MSDS section 7 - Handling and storage.

Thermal decomposition: No decomposition if stored and handled as prescribed/indicated.

Corrosion to metals: No data available.

Hazardous reactions:
No hazardous reactions if stored and handled as prescribed/indicated.

Hazardous decomposition products:
No hazardous decomposition products if stored and handled as prescribed/indicated.

11. Toxicological Information

Acute toxicity

Assessment of acute toxicity:
Of moderate toxicity after single ingestion. Virtually nontoxic after a single skin contact. Virtually nontoxic by inhalation.

Experimental/calculated data:
LD50 rat (oral): 367 mg/kg (BASF-Test)

LC50 rat (by inhalation): approx. 4.94 mg/l 4 h (OECD Guideline 403)

LD50 rat (dermal): > 2,000 mg/kg (BASF-Test)

Irritation

Assessment of irritating effects:
Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:
Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

Serious eyes damages/irritation rabbit: non-irritant (OECD Guideline 405)

Respiratory/Skin sensitization

Assessment of sensitization:
Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data:
Mouse Local Lymph Node Assay (LLNA) : Non-sensitizing. (OECD Guideline 429)

Germ cell mutagenicity

Assessment of mutagenicity:
The substance was mutagenic in various test systems with microorganisms and cell cultures; however, these results could not be confirmed in tests with mammals.

Reproductive toxicity

Assessment of reproduction toxicity:
In high doses a potential to impair fertility cannot be fully excluded.

12. Ecological Information

Ecotoxicity

Assessment of aquatic toxicity:
Acutely harmful for aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish:
LC50 (96 h) 87 mg/l, Leuciscus idus (DIN 38412 Part 15, static)
The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates:
EC50 (48 h) 182 mg/l, Daphnia magna (Directive 79/831/EEC, static)
The details of the toxic effect relate to the nominal concentration.

Aquatic plants:
EC50 (72 h) > 100 mg/l (growth rate), Scenedesmus subspicatus (OECD Guideline 201, static)
The details of the toxic effect relate to the nominal concentration.

Microorganisms/Effect on activated sludge:
EC50 (17 h) 3,490 mg/l, Pseudomonas putida (DIN 38412 Part 8, aerobic)

EC20 (180 min) approx. 900 mg/l, activated sludge (OECD Guideline 209, aerobic)
The product has not been tested. The statement has been derived from products of a similar structure and composition.

Persistence and degradability

Assessment biodegradation and elimination (H2O):
Readily biodegradable (according to OECD criteria). The product has not been tested. The statement has been derived from products of a similar structure and composition.

Elimination information:
90 - 100 % DOC reduction (22 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)
Analogous: Assessment derived from products with similar chemical character.

Bioaccumulation potential

Bioaccumulation potential:
Accumulation in organisms is not to be expected.

13. Disposal Considerations

Observe national and local legal requirements.

14. Transport Information

Land transport

ADR

Not classified as a dangerous good under transport regulations

RID

Not classified as a dangerous good under transport regulations

Inland waterway transport
ADNR

Not classified as a dangerous good under transport regulations

Sea transport

IMDG

Not classified as a dangerous good under transport regulations

Air transport
IATA/ICAO

Not classified as a dangerous good under transport regulations

15. Regulatory Information

Regulations of the European union (Labelling) / National legislation/Regulations

EC-Number: 200-362-1

Regulation 1272/2008/EC on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation 1907/2006/EC:

Hazard symbol(s)
Xn Harmful.

R-phrase(s)
R22 Harmful if swallowed.

S-phrase(s)
S2 Keep out of the reach of children.

Other regulations

16. Other Information

Vertical lines in the left hand margin indicate an amendment from the previous version.

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

Safety data for chlorpropamide

Glossary of terms on this data sheet.

The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers.

General

Synonyms: 1-(para-chlorophenylsulfonyl)-3-propylurea, N-(p-chlorobenzenesulfonyl)-N'-propylurea, 1-(p-chlorobenzenesulfonyl)-3-propylurea, 1-p-chlorophenyl-3-(propylsulfonyl)urea, 4-chloro-N-((propylamino)carbonyl)benzenesulfonamide, n-propyl-N'-(p-chlorobenzenesulfonyl)urea, 1-propyl-3-(p-chlorobenzenesulfonyl)urea, n-propyl-N'-p-chlorophenylsulfonylcarbamide, 4-chloro-4-((propylamino)carbonyl)benzenesulfonamide, N2-butyl-N1-p-chlorobenzenesulfonylurea, adiaben, asucrol, bioglumin, catanil, diabaril, daibechlor, diabenal, diabenese, diabenza, diabetoral, diabet-pages, diabexan, diabinese, glisema, meldian, mellinese, prodiaben
Use: anti-diuretic
Molecular formula: $C_{10}H_{13}ClN_2O_3S$
CAS No: 94-20-2
EC No: 202-314-5

Physical data

Appearance: white crystalline powder
Melting point: 127 - 129 C
Boiling point:
Vapour density:
Vapour pressure:
Specific gravity:
Flash point:
Explosion limits:

Autoignition temperature:

Stability

Stable. Combustible.

Toxicology

Harmful if swallowed, inhaled or in contact with the skin. Limited evidence of a carcinogenic effect.

Toxicity data

(The meaning of any toxicological abbreviations which appear in this section is given here.)
ORL-RAT LD50 2150 mg kg^{-1}
IPR-RAT LD50 580 mg kg^{-1}
IVN-RAT LD50 590 mg kg^{-1}

Risk phrases

(The meaning of any risk phrases which appear in this section is given here.)
R20 R21 R22 R40.

Personal protection

Safety glasses. Adequate ventilation.

Safety phrases

(The meaning of any safety phrases which appear in this section is given here.)
S22 S36.

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Chemicals & Laboratory Equipment

Health	1
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet

Ciprofloxacin Hydrochloride MSDS

Section 1: Chemical Product and Company Identification

Product Name: Ciprofloxacin Hydrochloride

Catalog Codes: SLC1510

CAS#: 86393-32-0

RTECS: Not available.

TSCA: TSCA 8(b) inventory: No products were found.

CI#: Not available.

Synonym: 3-Quinolinecarboxylic acid

Chemical Name: 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid monohydrochloride, monohydrate

Chemical Formula: C17-H18-F-N3-O3.HCl.H2O

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Ciprofloxacin Hydrochloride	86393-32-0	100

Toxicological Data on Ingredients: Not applicable.

Section 3: Hazards Identification

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...), halogenated compounds.

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions: Keep away from heat. Keep away from sources of ignition. Do not breathe dust.

Storage:
Keep container tightly closed. Keep container in a cool, well-ventilated area. Sensitive to light. Store in light-resistant containers.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline solid.)

Odor: Not available.

Taste: Not available.

Molecular Weight: 385.82 g/mole

Color: Yellowish. Yellow. (Light.)

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Not available.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, dust generation

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Sensitive to light.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
LD50: Not available. LC50: Not available.

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause skin irritation. May cause dermatitis. Eyes: May cause eye irritation with itching, burning sensation, tearing, decreased vision. May also cause conjunctival hyperemia, keratitis, keratopathy, lid edema, photophobia. Inhalation: Dust may cause respiratory tract irritation. Ingestion: May cause gastrointestinal tract irritation with nausea, vomiting, abdominal discomfort/pain, diarrhea, dry/painful mouth, bad taste in mouth, dyspepsia, heartburn, constipation, flatulence, pseudomembranous colitis, oral candidiasis. May also affect behavior/central nervous system. Symptoms may include headache, dizziness, fatigue, lethargy, malaise, drowsiness, restlessness, insomnia, nightmares, hallucinations, tremor, lightheadedness, irritability, confusion, ataxia, mania, weakness, psychotic reactions, depression, depersonalization, seizures. May also affect the kidneys and cause nephritis, hematuria, cylindruria, renal failure, urinary retention, polyuria, urethral bleeding, renal calculi, interstitial nephritis. It may also affect the skin (urticaria, dermatitis, photosensitivity, flushing, hypersensitivity, hyperpigmentation, rash, edema, erythema nodosum, cutaneous candidiasis), hearing (tinnitus, hearing loss), blood (leukopenia, anemia, leukocytosis, agranulocytosis, eosinophilia, pancytopenia)), cardiovascular system (hypertension, syncope, angina pectoris, palpitations, atrial flutter, postural hypotension, respiratory system(dyspnea, bronchospasm, pulmonary embolism, edema of the larynx or lungs, hemoptysis, hiccoughs, epistaxis), and liver (hepatic necrosis, cholestatic jaundice). Other symptoms may include blurred or double vision, eye pain, nystagmus; joint pain or stiffness, back, neck or chest pain; flareup of gout.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are more toxic than the product itself.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: No products were found.

Other Regulations: Not available.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
This product is not classified according to the EU regulations. Not applicable.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 04:56 PM

Last Updated: 11/01/2010 12:00 PM

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GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET

according to 2001/58/CE

985400

Review date: 14/01/2010
Printing date: 14/01/2010

1 IDENTIFICATION OF THE PRODUCT AND COMPANY

- **Product details**
- Trade name:
  COMPRITOL 888 ATO
- Article number:
  3123
- Application of the substance / the preparation
  Raw material for cosmetic and/or pharmaceutical uses.
- **Identification of the company :**
- Manufacturer/Supplier:
  Gattefossé sas
  36, chemin de Genas
  BP 603
  69804 Saint Priest cédex
  Tel.: (33) 04.72.22.98.00
  Fax : (33) 04.78.90.45.67
- Further information obtainable from:
  Commercial local Department.
- Information in case of emergency:
  Tel : (33) 04.72.22.98.00 / Site safety department.

2 COMPOSITION DATA ON INGREDIENTS

- **Chemical characterization:**
  Mixture of glycerol esters.
- Components : CAS No : EINECS No :
  Glyceryl Dibehenate 91052-55-0 (or 94201-62-4) 293-216-1 (or 303-650-6)
- Dangerous components:
  None

3 HAZARDS IDENTIFICATION

- **Hazard description:**
  None

4 FIRST AID MEASURES

- **General information :**
  No special measures required.
- **After inhalation:**
  No special measures required.
- **After skin contact:**
  Wash with water and soap and rinse thoroughly.
- **After eye contact:**
  Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing :**
  Drink copious amounts of water and provide fresh air. If necessary call for doctor.

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MATERIAL SAFETY DATA SHEET
according to 2001/58/CE

985400

Review date: 14/01/2010
Printing date: 14/01/2010

PRODUCT : COMPRITOL 888 ATO

(continued of page 1)

5 FIRE FIGHTING MEASURES

- **Suitable extinguishing agents:**
  CO_2, sand, extinguishing powder. Do not use water.
- **Protective equipment:**
  No special measures required.

6 ACCIDENTAL RELEASE MEASURES

- **Person-related safety precautions:**
  Not required.
  Particular danger of slipping on leaked/spilled product.
- **Measures for environmental protection:**
  Do not allow product to reach sewage system or any water course.
- **Measures for cleaning/collecting:**
  Wash with warm water.

7 HANDLING AND STORAGE

- **Handling:**
- Information for safe handling:
  No special measures required.
- Information about fire - and explosion protection:
  Keep ignition sources away - Do not smoke.
- **Storage:**
- Requirements to be met by storerooms and receptacles:
  No special requirements.

8 EXPOSURE CONTROLS AND PERSONAL PROTECTION

- General protective and hygienic measures:
  The usual precautionary measures are to be adhered to when handling chemicals.
- Breathing equipment : No necessary
- Hand protection : No necessary
- Eye protection : No necessary
- Body protection : Protective work clothing

9 PHYSICAL AND CHEMICAL PROPERTIES

Form:	Powder
Colour:	White-yellow
Odour:	Light
Boiling point/Boiling range:	> 150 °C
Drop point :	69,0 - 74,0°C (Mettler)
Flash point:	> 150 °C
Self igniting :	Product is not selfigniting.
Solubility in / Miscibility with	
water:	Insoluble.
organic solvents:	Soluble in many organic solvents.

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PRODUCT : COMPRITOL 888 ATO

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10 STABILITY AND REACTIVITY

- **Thermal decomposition / conditions to be avoided:**
  No decomposition if used according to specifications.
- Dangerous reactions
  Reacts with strong acids and oxidizing agents.
- **Dangerous decomposition products:**
  Incomplete combustion releases monoxyd carbon and dioxyd carbon.

11 TOXICOLOGICAL INFORMATION

- Acute toxicity by oral route :
- Concentration : 20 %
- Diluent : Olive oil
- Result :
. DL 50 :
>= 2000 mg/kg
- Expert conclusion : Not classified
- Primary cutaneous and corrosive irritation :
- Expert conclusion : Not classified
- Ocular irritation and reversibility :
- Concentration : Pure
- Expert conclusion : Not classified
- Ocular irritation (OI) :
- Concentration : 5 (TOX 95275)
- Diluent :
Kernel oil
- Result : 8,67
- Expert conclusion : Well tolerated
- Epicutaneous single patch test :
- Concentration : 10% (TOX 96283)
- Diluent :
Kernel oil
- Expert conclusion : Well tolerated

12 ECOLOGICAL INFORMATION

- General notes:
  Currently none ecological data on the product are available. Following data concern main compounds.
- **Indications about main compounds :**

FATTY ACIDS :
- Data about elimination :
Easily degradable.
Biodegradable (OECD classification).
- Ecological effects :
. Acute toxicity towards fishes :
LC 0 : >=100 mg/prod./l
. Acute toxicity towards bacteriums :
EC 0 : >= 100 mg prod./l
GLYCERIN :
- Data about elimination :
Biodegradable
- Acute toxicity toward fishes :
Lc 50 : > 1000 mg/l/96h

GB

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GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET
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(continued of page 3)

13 DISPOSAL CONSIDERATIONS

- Recommendation about product :
  Must be disposed of an incinerator.
- Recommendation:
  Disposal must be made according to official regulations.

14 TRANSPORT INFORMATON

- **Land transport ADR/RID (cross-border)**
  Not restricted
- **Inland shipping ADN:**
  Not restricted
- **Maritime transport IMDG:**
  Not restricted
- **Air transport ICAO-TI and IATA-DGR:**
  Not restricted

15 REGULATORY INFORMATION

- **Labelling according to EU guidelines:**
  The substance is not subject to classification according to the Directives 67/548/EEC and 88/379/EEC.
  All compounds of the substance are recorded into european inventory EINECS (European Inventory of Existing Chemical Substances)-Directives 79/831/EEC, sixth modification of directive 67/548/EEC.
- **International rules :**
- - USA :
  All compounds of the substance are recorded in the US inventory : TSCA (Toxic Substance Control Act).
- - Germany :
  Wassergefährdungsklasse (WGK) : 1 (little polluting)

16 OTHER INFORMATION

Regulatory requirements relative to the distribution of this MSDS : In accordance with the regulatory requirements, all information in the MSDS must be transmitted by the MSDS recipient to the health authorities, to any party receiving the products and to any other person likely to be exposed to the products.
Asterisks on life show modifications with regard to last chemical safety data sheet.

- **Liability clause :**

(continued on page 5)

GATTEFOSSÉ

MATERIAL SAFETY DATA SHEET
according to 2001/58/CE

985400

Review date: 14/01/2010
Printing date: 14/01/2010

PRODUCT : COMPRITOL 888 ATO

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The information contained in this data sheet is based on our knowledge of the related product on the date indicated, but does not amount to a guarantee in respect of the product's properties and does not give rise to any contractual legal tie. This information is given in utmost good faith. It cannot substitute for indispensable preliminary tests that must be conducted to ensure product suitability for each intended use. The user's attention is also drawn to the possible risks incurred if a product is used for a purpose other than its designed purpose. This data sheet does not under any circumstance replace knowledge and application by the user of all laws and regulations relevant to his own operations. The user shall be solely liable for the precautions taken relevant to the use made of the products. The list of related laws and regulations is given simply to help the user to fulfil the obligations incumbent upon him for use of the product. This must not be considered an exhaustive list and does not exempt the user from ensuring that he may possibly come under other obligations pursuant to laws or regulation other than those indicated relating to the possession and manipulation of the product for which he shall be solely liable.

Croscarmellose Sodium

No Registration or Login is Required For Quick Quote / Quick Offer.
If you are requesting more than 1 product, please use Shopping Cart features below.
Product :
Croscarmellose Sodium
CAS# :
74811-65-7
Synonym :
Sodium CMC
Formula :
-
Class :
Excipients - Food Colors - Binders and Tabletting Aids
Product Type :
-
Hazard :
0 Non-Regulated Material

SPECIFICATIONS

Color :
White or off white.
Contents of water soluble materials (%) :
1.0 - 10.0.
Appearance :
Free-flowing, fibrous powder.
Identification A, B, C :
Conforms.
pH (1%) :
5.0 - 7.0.
Heavy metals (ppm) :
<10.
Degree of substitution :
0.60 - 0.85.
Loss on drying (%) :
<10.0.
Organic volatile impurities :
Within limit.
Sodium chloride and sodium glycolate (%) :
<0.5.
Settling volume (ml) :
10 - 30.

1. IDENTIFIKACIJA TVARI/PRIPRAVKA I PODACI O PRAVNOJ ILI FIZIČKOJ OSOBI

- Naziv proizvoda: **Cutina HR Powder**

- Sinonimi:

- Šifra proizvoda:

- Namjena proizvoda: Za postizavanje konzistencije.

- Način uporabe: Dodaje se kao voštana masa u sve preparate za njegu kože, posebno one u stikovima.

- Proizvođač/dobavljač: **Cognis Deutschland GmbH&Co.KG,Henkelstr.67,40551 Düsseldorf**
Cos-Chem d.o.o.

Odgovorna osoba za STL: *Damir Markić* **e-mail:** info@coschem.hr

Adresa: **10000 Zagreb, Podgaj 2** Tel. 00-385-(0)1 467 3347

Faks 00-385-(0)1 467 3346

- Broj telefona službe za izvanredna stanja: **112**

- Broj telefona za medicinske informacije: **00-385-01-23-48-342**

2. IDENTIFIKACIJA OPASNOSTI

- Najvažnije opasnosti i učinci proizvoda: Ne smatra se rizičnim po zdravlje ili okoliš, prema važećim propisima.

na ljudsko zdravlje: Nema.

na okoliš: Nema.

fizikalno kemijske opasnosti: Nema.

- Posebne opasnosti: Fina prašina može stvarati upaljive smjese sa zrakom.

- Glavni simptomi učinaka:

Udisanje: nisu poznati

Koža: nisu poznati

Oči: nisu poznati

Gutanje: nisu poznati

- Pregled izvanrednih stanja: nema posebnih preporuka.

3. SASTAV/PODACI O SASTOJCIMA

- Tvar: ☐ **Pripravak** ☒

- Kemijski naziv kemikalije:

- CAS broj:

- Kemijski sastav pripravka (koncentracija / područje koncentracije):

Hidrogenirano ricinusovo ulje.

- Sastojci koji pridonose opasnosti proizvoda:

Naziv sastojka	%	EINECS/ CAS broj	Znak opasnosti	Oznaka upozorenja	Oznaka obavijesti
hidrogenirano ricinusovo ulje.	100	- 8001-78-3	-	-	

4. MJERE PRVE POMOĆI

- Mjere za pružanje prve pomoći:

- Općenito: U slučaju vidljivih zdravstvenih problema, potražiti medicinsku pomoć.

nakon udisanja: Vjerojatnost izlaganja mala. Nema podataka o učincima.

nakon dodira s kožom: Isprati tekućom vodom.

nakon dodira s očima: Odmah isprati tekućom vodom najmanje 10 minuta, po potrebi potražiti pomoć liječnika .

nakon gutanja: Isprati usnu šupljinu. Popiti 1-2 čaše vode. Po potrebi potražiti savjet liječnika .

- Napomena za osobu koja pruža prvu pomoć/liječnika:

5. MJERE ZA SUZBIJANJE POŽARA

- Sredstva za gašenje požara:

PRIKLADNA: Pjena, prah, CO_2,vodena magla.

NE SMIJU SE UPOTREBLJAVATI: nije poznato

- Protupožarne mjere za posebne opasnosti: nisu poznate

- Posebne metode za gašenje požara: nisu poznate

- Posebna oprema za zaštitu vatrogasaca: Koristiti samostalni uređaj za disanje na stlačeni zrak i vatrootpornu zaštitnu odjeću.

- Posebne opasnosti izloženosti: nisu poznate

- Opasni produkti (plinovi) izgaranja: Akrolein.

6. MJERE KOD SLUČAJNOG ISPUŠTANJA

- Osobne mjere opreza: Koristiti filtarsku polumasku.

- Mjere zaštite okoliša: Ne ispuštati u odvode, površinske ili podzemne vode.

- Način čišćenja i sakupljanja: Sakupiti mehanički, pa sav otpadni materijal staviti u spremnike koji se mogu čvrsto zatvoriti, te iste predati ovlaštenoj pravnoj osobi na zbrinjavanje.

- Dodatna upozorenja:

7. RUKOVANJE I SKLADIŠTENJE

- Rukovanje:

mjere opreza: Izbjegavati otvoreni plamen, kao i stvaranje prašine zbog opasnosti od eksplozije.

napuci za sigurno rukovanje: Ne ispuštati ostatke tvari u kanalizaciju.

- Skladištenje: tehničke mjere i uvjeti skladištenja:

PRIKLADNI: Spremnike držati dobro zatvorene i nakon upotrebe iste ponovo dobro zatvoriti. Skladištiti na suhom mjestu, na temperaturi < +30 °C.

IZBJEGAVATI:

- Ambalažni materijali:

PREPORUČENI: Originalni spremnik proizvođača (plastične vreće).

NEPRIKLADNI:

- Posebna uporaba:

8. NADZOR NAD IZLOŽENOŠĆU/OSOBNA ZAŠTITA

- Tehničke mjere za smanjenje izloženosti: Ako se stvaranje prašine uzrokovano rukovanjem ovom tvari ne može izbjeći, nužno je koristiti opremu za usisavanje, u radnim prostorima.

- Parametri nadzora:

Naziv opasne tvari	GVI Granična vrijednost izloženosti ppm	Biološke granične vrijednosti
C14-18 mono- i di-gliceridi	nema podataka	

- Osobna zaštitna sredstva za:

zaštitu dišnih puteva: Filtarska polumaska.

zaštitu ruku	Nisu potrebna.
zaštitu očiju	Zaštitne naočale.
zaštitu kože i tijela	Koristite odjeću koja pruža potpunu zaštitu kože (prirodna vlakna, poput pamuka) i obuću koja obuhvaća cijelo stopalo.

- Posebne higijenske mjere i mjere opreza: U radnom prostoru zabranjeno jesti, piti i pušiti. Nakon svakog prekida rada oprati ruke.

9 FIZIKALNA I KEMIJSKA SVOJSTVA

- Fizikalno stanje:

- Oblik:	kruto, praškast
- Boja:	bijela, lagano žućkasta
- Miris:	po masnoći

- pH vrijednost (navesti i konc. i temp):		nije poznato
- Vrelište/područje vrenja:	**°C**	nije poznato
- Talište/područje taljenja:	**°C**	nije poznato
- Temperatura raspada:	**°C**	nije poznato
- Plamište(DIN ISO 2592-81):	**°C**	> 200,0
- Temperatura samozapaljenja:	**°C**	nije poznato
- Granice eksplozivnosti:	**vol. %**	nije poznato
- Oksidirajuća svojstva:		nije poznato
- Tlak para:	**Pa**	nije poznato
- Gustoća para:	**kg/m^3**	nije poznato
- Gustoća:	**kg/m^3**	nije poznato
- Viskoznost:		nije primjenljivo
- Topljivost -kvalitativno (20°C) (uz naznaku otapala):	**g/L**	nije poznato
- Topljivost u vodi:	**g/L**	netopivo
- Koeficijent raspodjele-oktanol/voda	**logPow**	nije poznato
- Sadržaj hlapljivog:		nije poznato
- Ostalo:		

10. STABILNOST I REAKTIVNOST

- Stabilnost:	Stabilno na sobnoj temperaturi i pri normalnim uvjetima skladištenja i rukovanja.
- Uvjeti koje treba izbjegavati:	Otvoreni plamen i prekomjerno zagrijavanje.
- Materijali koje treba izbjegavati:	Nisu poznati ako se koristi za predviđenu namjenu.
- Opasni proizvodi raspada:	Ugljikovi oksidi i drugi nadražujući plinovi.

11. PODACI O TOKSIČNOSTI

- Akutno otrovanje:

oralno (LD_{50})	LD50 > 5000 mg proizvoda/kg tjelesne težine (eksperimentalno).
inhalacijsko (LC_{50})	nema podataka
dermalno (LD_{50})	nema podataka

- Lokalni učinci:

nadražaj kože	Ne nadražuje (analogija).
nadražaj očiju	Ne nadražuje (metoda: Draize-test).

osjetljivost kože	nema podataka
- Kronično trovanje ili dugotrajno izlaganje:	
- Učinak izlaganja	nema podataka
Jednokratno:	nema podataka
Višekratno:	nema podataka
Dugotrajno:	nema podataka
- Trenutni učinci:	nema podataka
- Odgođeni učinci:	nema podataka
- Posebni učinci (karcinogenost, mutagenost, reproduktivnost):	Nije mutageno (OECD 471).
- Dopunski podaci:	nema podataka

12. EKOLOŠKI PODACI

- Pokretljivost:		**Metoda:**
poznata ili predviđena raspodjela u prostoru	nema podataka	
površinska napetost	nema podataka	
apsorpcija/desorpcija	nema podataka	
druga fizikalno-kemijska svojstva (vidi odjeljak 9)		
- Postojanost/razgradljivost:		
biotička ili abiotička razgradnja:		
konačna biorazgradivost:	Dobra biorazgradivost. Pri testu lagane razgradivosti svi organski sastojci tvari postigli su razgradivost >60% BOD/COD ili oslobađanja CO2, ili >70% smanjenja DOC. Početne vrijednosti za kategoriju "lagano razgradivo" (tj. prema metodi OECD 301) su postignute.	
razgradnja uz prisutnost zraka i bez njega	nema podataka	
postojanost	nema podataka	
- Bioakumulacija:		
faktor biokoncentracije (BCF)	nema podataka	
- Učinci proizvoda na okoliš:		
na vodu	nema podataka	
na zrak	nema podataka	
na tlo	nema podataka	
- Ekotoksičnost:		
za vodene organizme	Akutna toksičnost na ribama: LC50 > 100 mg proizvoda /l (ISO 7346/2 (semistatično)).	
za organizme u tlu	nema podataka	
za biljke i kopnene životinje	nema podataka	
- Ostali podaci:	Akutna bakterijska toksičnost:	EC0 > 100 mg proizvoda /l (OECD 209).

13. POSTUPANJE S OTPADOM

- Način postupanja s otpadom:	
Ostaci od proizvoda:	Predviđeno predavanje ovlaštenoj pravnoj osobi za zbrinjavanje otpada.
Onečišćena ambalaža:	Predviđeno predavanje ovlaštenoj pravnoj osobi za zbrinjavanje otpada.
- Važeći mjesni propisi:	Zakon otpadu (NN 178/04), Pravilnik o vrstama otpada, Pravilnik o postupanju s ambalažnim otpadom , Uredba za postupanje s opasnim otpadom .

14. PODACI O PRIJEVOZU

- Klasifikacijske oznake za prijevoz: Proizvod ne podliježe zakonskim propisima.

Naziv opasne kemikalije prema međunarodnim ugovorima o prijevozu opasnih tvari:

kopneni prijevoz (cestovni/željeznički ADR, RID):

UN broj: **klasa:** **skupina pakiranja:**

vodeni putovi u zemlji (ADNR):

UN broj: **klasa:** **skupina pakiranja:**

pomorski prijevoz (IMDG):

UN broj: **klasa:** **skupina pakiranja:**

zračni prijevoz (ICAO/IATA):

UN broj: **klasa:** **skupina pakiranja:**

- Dodatni propisi: Zakon o prijevozu opasnih tvari.

- Posebne mjere opreza i uvjeti prijevoza:

15. PODACI O PROPISIMA

- Primjenjivi propisi: Zakon o kemikalijama (NN 150/05), njegovi podzakonski akti i Pravilnik o maksimalno dopustivim koncentracijama štetnih tvari u atmosferi radnih prostorija i prostor MDK i o biološkim graničnim vrijednostima BGV.

- Podaci o opasnosti i mjerama sigurnosti (prema naljepnici):

Znak opasnosti Nema.

Oznake upozorenja R: Nema.

Oznake obavjesti S: S 2: Čuvati izvan dohvata djece

16. OSTALI PODACI

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MATERIAL SAFETY DATA SHEET

FRUCTOFIN®

1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND THE COMPANY UNDERTAKING

SUBSTANCE/PREPARATION:
FRUCTOSE
TRADENAME/SYNONYMS:
FRUCTOFIN®C; FRUCTOFIN®CM, FRUCTOFIN®CFP, FRUISANA
CHEMICAL FAMILY:
KETOHEXOSE
MOLECULAR FORMULA:
$C_6H_{12}O_6$
MOLECULAR WEIGHT:
180.16
EINECS NUMBER:
200-333-3
COMPANY:
DANISCO (UK) LIMITED
41-51 BRIGHTON ROAD
REDHILL
SURREY
RH1 6YS
UNITED KINGDOM

TELEPHONE
+ 44 1737 773 732
TELEFAX
+ 44 1737 773117

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT	CAS RN	PERCENT
FRUCTOSE	57-48-7	Min. 99.5

3. HAZARD IDENTIFICATION

SKIN CONTACT:
SHORT TERM EFFECTS: No information is available.
LONG TERM EFFECTS: May cause irritation in susceptible individuals.
EYE CONTACT:
SHORT TERM EFFECTS: No information is available.
LONG TERM EFFECTS: May cause irritation with direct contact in susceptible individuals.
INHALATION:
SHORT TERM EFFECTS: No information is available.
LONG TERM EFFECTS: Prolonged exposure as a nuisance particle may result in respiratory irritation in susceptible individuals or those with respiratory conditions.
INGESTION:
SHORT TERM EFFECTS: No information is available on significant adverse effects.
LONG TERM EFFECTS: Fructose is approved for food use and is non toxic.

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4. FIRST AID MEASURES

SKIN CONTACT:
Remove contaminated clothing and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains. Seek medical attention if needed.

EYE CONTACT:
Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (at least 15-20 minutes). Obtain medical attention immediately.

INHALATION:
Remove from exposure area immediately. Treat symptomatically and supportively. Seek medical attention if needed.

ANTIDOTES:
No specific antidote. Treat symptomatically and supportively.

5. FIRE-FIGHTING MEASURES

FIRE CONTROL
Dry chemical, carbon dioxide, water spray or regular foam
For larger fires, use water spray, fog or regular foam.

FIRE AND EXPLOSION HAZARD:
Slight fire hazard when exposed to heat or flame.
Dust-air mixtures may ignite or explode.

FIRE-FIGHTING:
Move container from fire area if possible without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal (1993 Emergency Response Guidebook. RSPA P 5800.6, Guide Page 31).

Use agents suitable for type of surrounding fire. Avoid breathing hazardous vapours, keep upwind.

6. ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL SPILL:
Sweep up and place in suitable containers for disposal. Do not flush spilled material into sewer.

7. HANDLING AND STORAGE

HANDLING:
Provide local exhaust or general dilution ventilation system.

STORAGE:
Observe all appropriate regulations when storing this substance.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE CONTROLS:

No permissible exposure limits established by Danisco, Australia, Belgium, Denmark, France, Germany, United Kingdom (HSE) or United States (ACGIH, OSHA).

PERSONAL PROTECTION:

EYE PROTECTION:
Employee should wear splash-proof or dust resistant safety goggles to prevent eye contact with this substance.

EMERGENCY EYE WASH:
Where there is any possibility that an employee's eyes may be exposed to this substance, the employer should provide an eye wash fountain within the immediate work area for emergency use.

CLOTHING:
Employee should wear appropriate protective clothing and equipment to prevent repeated prolonged skin contact with this substance.

GLOVES:
Employee should wear appropriate protective gloves to prevent contact with this substance.

RESPIRATOR:
The following respirators are recommended based on information found in the physical data, toxicity and health effects sections. They are ranked in order from minimum to maximum respiratory protection.

The specific respirator selected must be based on contamination levels found in the work place and the specific operation, and must be jointly approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH-MSHA). Contamination levels in the work place must not exceed the working limits of the respirator

i) Any dust and mist respirator with a full facepiece.

ii) Any air-purifying full facepiece respirator with a high-efficiency particulate filter.

iii) Any powered air-purifying respirator with a tight-fitting facepiece and high-efficiency particulate filter.

iv) Any type 'C' supplied-air respirator with a full facepiece operated in pressure-demand or other positive pressure mode or with a full facepiece, helmet or hood operated in continuous-flow mode.

FOR FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS

v) Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

vi) Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure-demand or other positive-pressure mode.

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9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE:	White crystalline or milled powder with a sweet taste.
FLASH POINT:	No data available
AUTOIGNITION TEMPERATURE:	No data available
LOWER EXPLOSION LIMIT:	No data available
UPPER EXPLOSION LIMIT:	No data available
BOILING POINT:	N/A
MELTING POINT:	102-105°C
VAPOUR PRESSURE:	No data available
VAPOUR DENSITY:	N/A
SPECIFIC GRAVITY:	N/A
WATER SOLUBILITY:	Very soluble (approximately 3.5g/ml @ 20°C)
pH:	4.5 - 7.0 (10% w/v solution)
ODOUR THRESHOLD:	Odourless
EVAPORATION RATE:	N/A
SOLVENT SOLUBILITY:	Soluble in alcohols, ether.

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID:
May burn but does not ignite readily. Avoid contact with strong oxidisers, excessive heat, sparks, or open flame.

REACTIVITY:
Stable under normal temperatures and pressures.

INCOMPATIBILITIES:
No data available.

HAZARDOUS DECOMPOSITION:
Thermal decomposition may release toxic and/or hazardous gases.

POLYMERISATION:
Hazardous polymerisation has not been reported to occur under normal temperatures and pressures.

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11. TOXICOLOGY AND INFORMATION

TOXICITY DATA:
Approved for use in food. Sugar and food ingredient found in nature, widely used in the food industry, considered non hazardous.

CARCINOGEN STATUS:
Not a known or anticipated carcinogen.

ACUTE TOXICITY LEVEL:
Relatively non-toxic by ingestion.

TARGET EFFECTS:
No data available.

HEALTH EFFECTS

No LD50/LC50 information found relating to normal routes of occupational exposure.

INHALATION:
ACUTE EXPOSURE - No data available.
CHRONIC EXPOSURE - No data available.

SKIN CONTACT:
ACUTE EXPOSURE - No data available.
CHRONIC EXPOSURE - No data available.

EYE CONTACT:
ACUTE EXPOSURE - No data available.
CHRONIC EXPOSURE - No data available.

INGESTION:
ACUTE EXPOSURE - No data available.
CHRONIC EXPOSURE – Approved for food use.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL IMPACT RATING (0-4):
No data available

ACUTE AQUATIC TOXICITY:
No data available.

DEGRADABILITY:
No data available.

LOG BIOCONCENTRATION FACTOR (BCF):
No data available.

LOG OCTANOL/WATER PARTITION COEFFICIENT:
No data available.

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13. DISPOSAL CONSIDERATIONS

Observe all federal, state and local regulations when disposing of this substance.

14. TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release.

No classification currently assigned.

15. REGULATORY INFORMATION

EUROPEAN UNION CLASSIFICATION AND LABELLING REQUIREMENTS:
European Union labelling requirements not determined.

16. OTHER INFORMATION

INFORMATION ON HAZARD LABELLING:
To be determined.

REFERENCES:
To be determined.

This MSDS is based on a review of Danisco files, literature references, toxicology handbooks and published MSDS's on identical or related materials, and is believed to be accurate. However, no warranty is expressed or implied regarding the accuracy of this data or the results to be obtained from their use. Users should make their own investigations to determine the suitability of the information for their particular purposes. Nothing herein shall constitute permission, inducement or recommendation to practice any invention covered by any patent owned by Danisco Sweeteners or by others, nor as a recommendation to use any product or to practice any process in violation of any law or government regulations.

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Sicherheitsdatenblatt
gemäß 91/155/EWG

Druckdatum: 19.02.2008 überarbeitet am: 22.07.2003

1 Stoff-/Zubereitungs- und Firmenbezeichnung

· Angaben zum Produkt

· Handelsname: DICALCIUMPHOSPHAT wasserfrei
· Verwendung des Stoffes / der Zubereitung Industriechemikalie

· Hersteller/Lieferant:
BRENNTAG CEE GmbH
Linke Wienzeile 152
A - 1060 WIEN
Tel.: 0043/1/59995-0
Fax: 0043/1/5970200

· Auskunftgebender Bereich:
Abteilung Produktsicherheit, DW 1118
Vergiftungsinformationszentrale: 01 - 406 43 43
· Notfallauskunft: Vergiftungsinformationszentrale: 01/406 43 43

2 Zusammensetzung/Angaben zu den Bestandteilen

· CAS-Nr. Bezeichnung
7757-93-9 sek. Calciumphosphat
· Identifikationsnummer(n)
· EINECS-Nummer (EG-Nummer): 2318261

3 Mögliche Gefahren

· Gefahrenbezeichnung: ungefährlich
· Besondere Gefahrenhinweise für Mensch und Umwelt: entfällt

4 Erste-Hilfe-Maßnahmen

· nach Hautkontakt: Sofort mit Wasser abwaschen.
· nach Augenkontakt: Augen bei geöffnetem Lidspalt mehrere Minuten mit fließendem Wasser spülen.
· nach Verschlucken: Bei anhaltenden Beschwerden Arzt konsultieren.

5 Maßnahmen zur Brandbekämpfung

· Geeignete Löschmittel: Feuerlöschmaßnahmen auf die Umgebung abstimmen.
· Besondere Gefährdung durch den Stoff, seine Verbrennungsprodukte oder entstehende Gase:
Beim Erhitzen oder im Brandfalle Bildung giftiger Gase möglich.
· Besondere Schutzausrüstung: Umgebungsluftunabhängiges Atemschutzgerät tragen.

6 Maßnahmen bei unbeabsichtigter Freisetzung:

· Personenbezogene Vorsichtsmaßnahmen:
Staubbildung vermeiden.
Persönliche Schutzkleidung tragen.
· Umweltschutzmaßnahmen: Nicht in die Kanalisation oder in Gewässer gelangen lassen.
· Verfahren zur Reinigung/Aufnahme:
Mechanisch aufnehmen.
Das aufgenommene Material vorschriftsmäßig entsorgen.

7 Handhabung und Lagerung

· Handhabung:
· Hinweise zum sicheren Umgang:
Staubbildung vermeiden.
Behälter dicht geschlossen halten.

(Fortsetzung auf Seite 2)

Sicherheitsdatenblatt
gemäß 91/155/EWG

Druckdatum: 19.02.2008 überarbeitet am: 22.07.2008

Handelsname: DICALCIUMPHOSPHAT wasserfrei

(Fortsetzung von Seite 1)

· **Hinweise zum Brand- und Explosionsschutz:** Das Produkt ist nicht brennbar.

· **Lagerung:**
· **Anforderung an Lagerräume und Behälter:** Keine besonderen Anforderungen.
· **Zusammenlagerungshinweise:** nicht erforderlich
· **Weitere Angaben zu den Lagerbedingungen:** In gut verschlossenen Gebinden kühl und trocken lagern.
· **Lagerklasse:** VCI: 11/13
· **VbF-Klasse:** entfällt

8 Expositionsbegrenzung und persönliche Schutzausrüstung

· **Zusätzliche Hinweise zur Gestaltung technischer Anlagen:** Keine weiteren Angaben, siehe Punkt 7.

· **Bestandteile mit arbeitsplatzbezogenen, zu überwachenden Grenzwerten:** Entfällt
· **Zusätzliche Hinweise:** Als Grundlage dienten die bei der Erstellung gültigen Listen.

· **Persönliche Schutzausrüstung:**
· **Allgemeine Schutz- und Hygienemaßnahmen:**
Die üblichen Vorsichtsmaßnahmen beim Umgang mit Chemikalien sind zu beachten.
· **Atemschutz:** Staubmaske
· **Handschutz**
Handschuhe aus Kunststoff.
Handschuhe aus Gummi.
Das Handschuhmaterial muss undurchlässig und beständig gegen das Produkt / den Stoff / die Zubereitung sein.
Aufgrund fehlender Tests kann keine Empfehlung zum Handschuhmaterial für das Produkt / die Zubereitung / das Chemikaliengemisch abgegeben werden.
Auswahl des Handschuhmaterials unter Beachtung der Durchbruchzeiten, Permeationsraten und der Degradation.
· **Handschuhmaterial**
Die Auswahl eines geeigneten Handschuhs ist nicht nur vom Material, sondern auch von weiteren Qualitätsmerkmalen abhängig und von Hersteller zu Hersteller unterschiedlich.
· **Durchdringungszeit des Handschuhmaterials**
Die genaue Durchbruchzeit ist beim Schutzhandschuhhersteller zu erfahren und einzuhalten.
· **Augenschutz:** nicht erforderlich.
· **Körperschutz:** Arbeitsschutzkleidung.

9 Physikalische und chemische Eigenschaften

· **Allgemeine Angaben**	
Form:	fast
Farbe:	weiß
Geruch:	geruchlos
· **Zustandsänderung**	
Schmelzpunkt/Schmelzbereich:	ca. 1350°C
Siedepunkt/Siedebereich:	nicht bestimmt
· **Flammpunkt:**	nicht anwendbar
· **Entzündlichkeit (fest, gasförmig):**	Der Stoff ist nicht entzündlich.
· **Explosionsgefahr:**	Das Produkt ist nicht explosionsgefährlich.
· **Dichte:**	Nicht bestimmt
· **Schüttdichte bei 20°C:**	ca. 900 kg/m3
· **Löslichkeit in / Mischbarkeit mit Wasser:**	unlöslich

(Fortsetzung auf Seite 3)

Sicherheitsdatenblatt
gemäß 91/155/EWG

Druckdatum: 19.02.2008 überarbeitet am: 22.07.2003

Handelsname: DICALCIUMPHOSPHAT wasserfrei

(Fortsetzung von Seite 2)

· pH-Wert (100 g/l) bei 20°C: ca. 7

10 Stabilität und Reaktivität

· **Thermische Zersetzung / zu vermeidende Bedingungen:**
Keine Zersetzung bei bestimmungsgemäßer Verwendung.
· **Zersetzung beginnt bei:** ca. 420°C Diphosphat-Bildung.
· **Gefährliche Reaktionen** Keine gefährlichen Reaktionen bekannt.
· **Gefährliche Zersetzungsprodukte:** keine

11 Angaben zur Toxikologie

· **Akute Toxizität:**
· **Primäre Reizwirkung:**
· **an der Haut:** Keine Reizwirkung
· **am Auge:** Keine Reizwirkung
· **Sensibilisierung:** Keine sensibilisierende Wirkung bekannt

12 Angaben zur Ökologie

· **Allgemeine Hinweise:**
Im allgemeinen nicht wassergefährdend
Nicht in das Grundwasser, in Gewässer oder in die Kanalisation gelangen lassen.

13 Hinweise zur Entsorgung

· **Produkt:**
· **Empfehlung:** Kleinere Mengen können gemeinsam mit Hausmüll deponiert werden.
· **Abfallschlüsselnummer:**
51541 nach ÖNORM S 2100
Bez.: sonstige Salze, schwerlöslich
Entsorgungshinweise:
Chemisch-physikalische Behandlung: nicht geeignet
Biologische Behandlung: nicht geeignet
Thermische Behandlung: nicht geeignet
Deponierung: Konditionierung erforderlich
· **Ungereinigte Verpackungen:**
· **Empfehlung:** Entsorgung gemäß den behördlichen Vorschriften.

14 Transportvorschriften

· **Landtransport ADR/RID und GGVS/GGVE (grenzüberschreitend/Inland):**
· **ADR/RID-GGVS/E Klasse:** -
· **Transport/weitere Angaben:** Kein Gefahrgut im Sinne der Transportvorschrift.

15 Österreichische und EU-Vorschriften

· **Kennzeichnung nach EWG-Richtlinien:**
Der Stoff ist nicht kennzeichnungspflichtig nach EG-Listen oder sonstigen uns bekannten Literaturquellen.
Die beim Umgang mit Chemikalien üblichen Vorsichtsmaßnahmen sind zu beachten.

(Fortsetzung auf Seite 4)

Sicherheitsdatenblatt
gemäß 91/155/EWG

Druckdatum: 19.02.2008 überarbeitet am: 22.07.2003

Handelsname: DICALCIUMPHOSPHAT wasserfrei

(Fortsetzung von Seite 3)

· **Nationale Vorschriften:**
Der Stoff oder die Zubereitung ist nicht gefährlich im Sinne des Chemikaliengesetzes.

· **Störfallverordnung:** Störfallverordnung, Anhang: nicht genannt.

· **Klassifizierung nach VbF:** entfällt

· **Wassergefährdungsklasse:** Im allgemeinen nicht wassergefährdend.

16 Sonstige Angaben:

Die Angaben stützen sich auf den heutigen Stand unserer Kenntnisse, sie stellen jedoch keine Zusicherung von Produkteigenschaften dar und begründen kein vertragliches Rechtsverhältnis.

· **Datenblatt ausstellender Bereich:** Abteilung Produktsicherheit
· **Ansprechpartner:** Fr.Ing.Marsich

BRENNTAG

SAFETY DATA SHEET according to EC directive 2001/58/EC

DICALCIUMPHOS C92-14 2HYD PLV PH S25KG

Version 1.0 Print Date 16.12.2010
Revision Date 16.01.2007

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product information

Trade name	:	DICALCIUMPHOS C92-14 2XSD PLV PH S25KG
Use	:	Industrialchemicals
Supplier	:	Brenntag UBE GmbH Dieselstrasse 152 AT 1060 Wien
Responsible Department	:	Abteilung Produktsicherheit
Telephone	:	+43 (1) 599 9 50
Telefax	:	+43 (1) 597 0 200
Emergency telephone number	:	Vergiftungsinformationszentrale: +43 (1) 406 43 43

2. COMPOSITION/INFORMATION ON INGREDIENTS

Components

Calcium hydrogen phosphate dihydrate

CAS-No. : 7789-77-7 EU-No.: 231-826-1

3. HAZARDS IDENTIFICATION

Other information

The product does not need to be labeled in accordance with EU directives or respective national laws.

4. FIRST AID MEASURES

Inhalation	:	Remove to fresh air. Give oxygen. Consult physician.
Skin contact	:	Wash off with soap and water.
Eye contact	:	Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist.
Ingestion	:	Clean mouth with water and drink afterwards plenty of water. If symptoms persist, call a physician.

6. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray, foam, dry powder or CO_2. Use extinguishing measures that are appropriate to the circumstances and the surrounding environment.
Special protective equipment for fire-fighters	:	Wear personal protective equipment. In case of insufficient ventilation, wear suitable respiratory equipment.

BRENNTAG

SAFETY DATA SHEET according to EC directive 2001/58/EC

DICALCIUMPHOS C92-14 2HYD PLV PH S25KG

Version 1.0 Print Date 16.12.2010
Revision Date 16.01.2007

Additional advice : The product is dangerous.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Avoid dust formation.
Environmental precautions : Do not flush into surface water or sewer system.
Methods for cleaning up : Use mechanical handling equipment. The material can be container must be disposed of as hazardous waste. Rinse with water.

7. HANDLING AND STORAGE

Handling

Advice on safe handling : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Advice on protection against fire and explosion : The product is not flammable. No special precautions required.

Storage

Requirements for storage areas and containers : Keep container tightly closed in a dry, cool and well-ventilated place.
German storage class : 13/11: Non combustible solids; Packaging possibly combustible

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection : Dust mask
Hand protection : Impervious gloves. The glove material has to be impermeable and resistant to the product/ the substance / the preparation. The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. The breakthrough time of the glove material has to be found out by the manufacturer of the protective gloves and has to be observed. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Eye protection : Safety glasses
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

Engineering measures

BRENNTAG

SAFETY DATA SHEET according to EC directive 2001/58/EC

DICALCIUMPHOS C92-14 2HYD PLV PH S25KG

Version 1.0 Print Date 16.12.2010
Revision Date 16.01.2007

Refer to protective measures listed in sections 7 and 8.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	:	powder
Colour	:	white
Odour	:	odourless

Safety data

Melting range	:	ca. 1.360 °C
Flash point	:	not applicable
Flammability (solid, gas)	:	does not ignite
Explosive properties	:	Product is not explosive.
Bulk density	:	ca. 500 - 650 kg/m3
Water solubility	:	insoluble
pH	:	ca. 7,5; 10 g/l; 20 °C

10. STABILITY AND REACTIVITY

Hazardous decomposition products	:	None known.
Hazardous reactions	:	None known.
General advice	:	No decomposition if stored and applied as directed.

11. TOXICOLOGICAL INFORMATION

Ingestion	:	LD50 rat > 2.000 mg/kg
Skin contact	:	No skin irritation
Eye contact	:	No eye irritation
Sensitization	:	not sensitising
Further information	:	No data is available on the product itself. Health injuries are not known or expected under normal use.

12. ECOLOGICAL INFORMATION

Elimination information (persistence and degradability)

Biodegradability	:	The methods for determining the biological degradability are not applicable to inorganic substances.

Further information on ecology

Additional ecological advice	:	Do not flush into surface water or sewer system.

P1369 3/5 EN

BRENNTAG

SAFETY DATA SHEET according to EC directive 2001/58/EC

DICALCIUMPHOS C92-14 2HYD PLV PH S25KG

Верзион 1.0 Принт Дате 16.12.2010
Ревизион Дате 16.01.2007

инфрматион

13. DISPOSAL CONSIDERATIONS

Продуцт : Депосал тогетхер них нормал васте ис нот аллоwед. Специал депосал реqуиред ацординг то лоцал регулатионс. До нот лет продуцт ентер драинс. Цонтацт мануфацтурер.

Пацкагинг : И ацорданце них лоцал анд натионал регулатионс. Диспосе оф ас унусед продуцт.

14. TRANSPORT INFORMATION

ADR: Нот дангерус гоодс

RID: Нот дангерус гоодс

IMDG: Нот дангерус гоодс

IATA: Нот дангерус гоодс

15. REGULATORY INFORMATION

Labelling according to EC Directives
Тхе продуцт доес нот неед то бе лабелед и ацорданце них ЕЦ дирецтивес ор респецтиве натионал ланс.

National legislation

Ваде Цоде : 51540
Регулатион : Тхе субстанце ор препаратион ис нот дангерус ацординг то тхе аустриан цхемицал легислатион.

16. OTHER INFORMATION

Further information

BRENNTAG

SAFETY DATA SHEET according to EC directive 2001/58/EC

DICALCIUMPHOS C92-14 2HYD PLV PH S25KG

Верзион 1.0 Принт Дате 16.12.2010
Ревизион Дате 16.01.2007

Тхе информатион провидед ин тхис Сафету Дата Схеет ис цоррецт то тхе бест оф оур кноwледге, информатион анд белиеф ат тхе дате оф итс публицатион. Тхе информатион гивен ис десигнед онлу ас а гуиданце фор сафе хандлинг, усе, процессинг, стораге, транспортатион, диспосал анд релеасе анд ис нот то бе цонсидеред а wарранту ор qуалиту специфицатион. Тхе информатион релатес онлу то тхе специфиц материал десигнатед анд мау нот бе валид фор суцх материал усед ин цомбинатион wитх анu отхер материалс ор ин анu процесс, унлесс специфиед ин тхе теxт. Рестрицтед то профессионал усерс. Аттентион - Авоид еxпосуре - обтаин специал инструцтионс бефоре усе.

Тхис сафету дата схеет онлу цонтаинс информатион релатинг то сафету анд доес нот реплаце анu продуцт информатион ор продуцт специфицатион.

Индицатес упдатед сецтион.

ScienceLab.com
Chemicals & Laboratory Equipment

Material Safety Data Sheet
Diltiazem Hydrochloride MSDS

Section 1: Chemical Product and Company Identification

Product Name: Diltiazem Hydrochloride

Catalog Codes: SLD2647

CAS#: 33286-22-5

RTECS: DL0310000

TSCA: TSCA 8(b) inventory: No products were found.

CI#: Not available.

Synonym:

Chemical Name: Diltiazem Hydrochloride

Chemical Formula: C22-H26-N2-O4-S.HCL

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: 1-800-901-7247
International Sales: 1-281-441-4400
Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Diltiazem Hydrochloride	33286-22-5	100

Toxicological Data on Ingredients: Diltiazem Hydrochloride: ORAL (LD50): Acute: 560 mg/kg [Rat]. 508 mg/kg [Mouse].

Section 3: Hazards Identification

Potential Acute Health Effects: Hazardous in case of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Classified Development toxin [POSSIBLE]. The substance is toxic to liver, gastrointestinal tract, cardiovascular system, skin, central nervous system (CNS). Repeated or prolonged exposure to the substance can produce target organs damage.

Section 4: First Aid Measures

Eye Contact: Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.

Skin Contact: No known effect on skin contact, rinse with water for a few minutes.

Serious Skin Contact: Not available.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

Serious Inhalation: Not available.

Ingestion:
Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...), sulfur oxides (SO2, SO3...).

Fire Hazards in Presence of Various Substances: Not available.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep locked up Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes Wear suitable protective clothing In case of insufficient ventilation, wear suitable respiratory equipment If ingested, seek medical advice immediately and show the container or the label.

Storage:
Keep container dry. Keep in a cool place. Ground all equipment containing material. Carcinogenic, teratogenic or mutagenic materials should be stored in a separate locked safety storage cabinet or room.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Splash goggles. Lab coat.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid.

Odor: Not available.

Taste: Not available.

Molecular Weight: 450.99 g/mole

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: 212°C (413.6°F)

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Not available.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Not available.

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: No.

Section 11: Toxicological Information

Routes of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 508 mg/kg [Mouse].

Chronic Effects on Humans:
DEVELOPMENTAL TOXICITY: Classified Development toxin [POSSIBLE]. The substance is toxic to liver, gastrointestinal tract, cardiovascular system, skin, central nervous system (CNS).

Other Toxic Effects on Humans: Hazardous in case of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans: Not available.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations:
California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Diltiazem Hydrochloride California prop. 65: This product contains the following ingredients for which the State of California has found to cause reproductive harm (female) which would require a warning under the statute: Diltiazem Hydrochloride California prop. 65: This product contains the following ingredients for which the State of California has found to cause reproductive harm (male) which would require a warning under the statute: Diltiazem Hydrochloride California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: Diltiazem Hydrochloride TSCA 8(b) inventory: No products were found.

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
R22- Harmful if swallowed. R40- Possible risks of irreversible effects.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: j

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Not applicable. Lab coat. Not applicable. Splash goggles.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 05:10 PM

Last Updated: 11/01/2010 12:00 PM

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Dr. Paul Lohmann®

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.04.2011 Revision: 03.12.2010

1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: ferrous fumarate

· Article number: E25
· CAS Number:
141-01-5
· EINECS Number:
205-447-7
· Relevant identified uses of the substance or mixture and uses advised against
· Application of the substance / the preparation
Pharma Active Ingredient
Food additive

· Details of the supplier of the safety data sheet
· Manufacturer/Supplier:
Dr. Paul Lohmann GmbH KG
Hauptstraße 2
D-31860 Emmerthal
GERMANY
MSDS@lohmann-chemikalien.de

· Further information obtainable from: Product safety department
· Emergency telephone number: During normal opening times: +49 5155 63-0

2 Hazards identification

· Classification of the substance or mixture
· Classification according to Regulation (EC) No 1272/2008
The substance is not classified according to the CLP regulation.

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

· Label elements
· Labelling according to Regulation (EC) No 1272/2008 Void
· Hazard pictograms Void
· Signal word Void
· Hazard statements Void
· Other hazards
· Results of PBT and vPvB assessment
· PBT: Not applicable.
· vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Substances
· CAS No. Description
141-01-5 ferrous fumarate
· Identification number(s)
· EINECS Number: 205-447-7

4 First aid measures

· Description of first aid measures
· General information: No special measures required.
· After inhalation: Supply fresh air; consult doctor in case of complaints.
· After skin contact: Generally the product does not irritate the skin.
· After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

(Contd. on page 2)

Dr. Paul Lohmann®

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.04.2011 Revision: 03.12.2010

Trade name: ferrous fumarate

(Cont. of page 1)

· After swallowing: If symptoms persist consult doctor.

5 Firefighting measures

· Extinguishing media
· Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· Special hazards arising from the substance or mixture
In case of fire, the following can be released:
Carbon monoxide (CO)
· Advice for firefighters
· Protective equipment:
Wear self-contained respiratory protective device.
Do not inhale explosion gases or combustion gases.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures Not required.
· Environmental precautions: Do not allow to enter sewers/ surface or ground water.
· Methods and material for containment and cleaning up: Pick up mechanically.
· Reference to other sections No dangerous substances are released.

7 Handling and storage

· Handling:
· Precautions for safe handling Prevent formation of dust.
· Information about fire - and explosion protection: No special measures required.

· Conditions for safe storage, including any incompatibilities
· Storage:
· Requirements to be met by storerooms and receptacles: No special requirements.
· Information about storage in one common storage facility: Store away from oxidizing agents.
· Further information about storage conditions:
Store in cool, dry conditions in well sealed receptacles.
Protect from exposure to the light.

8 Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

· Control parameters

· Ingredients with limit values that require monitoring at the workplace:	
141-01-5 ferrous fumarate	
WEL	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³ as Fe

· Additional information: The lists valid during the making were used as basis.

· Exposure controls
· Personal protective equipment:
· General protective and hygienic measures:
The usual precautionary measures are to be adhered to when handling chemicals.
· Respiratory protection: Not required.

(Cont. on page 3)

Dr. Paul Lohmann®

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.04.2011 Revision: 03.12.2010

Trade name: ferrous fumarate

(Contd. of page 2)

· Protection of hands:
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· Material of gloves
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· Penetration time of glove material
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· Eye protection: Safety glasses

9 Physical and chemical properties

· Information on basic physical and chemical properties
· General Information
· Appearance:
Form: Powder
Colour: Red-brown
· Odour: Nearly odourless

· Change in condition
Melting point/Melting range: 280°C
Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Danger of explosion: Not determined.

· Density at 20°C: 2.44 g/cm³

· Solubility in / Miscibility with water at 25°C: 1.4 g/l

10 Stability and reactivity

· Reactivity
· Chemical stability
· Thermal decomposition/ conditions to be avoided: No decomposition if used according to specifications.
· Possibility of hazardous reactions No dangerous reactions known.
· Hazardous decomposition products: Carbon monoxide and carbon dioxide

11 Toxicological information

· Information on toxicological effects
· Acute toxicity:

· LD/LC50 values relevant for classification:		
Oral	LD50	3850 mg/kg (rat)

· Primary irritant effect:
· on the skin: No irritant effect.
· on the eye: No irritating effect.
· Sensitization: No sensitizing effects known.

(Contd. on page 4)

Dr. Paul Lohmann®

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.04.2011 Revision: 03.12.2010

Trade name: ferrous fumarate

(Contd. of page 3)

· Additional toxicological information:
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
The substance is not subject to classification according to the latest version of the EU lists.

12 Ecological information

· Toxicity
· Aquatic toxicity: No further relevant information available.
· Persistence and degradability biodegradable
· Additional ecological information:
· General notes:
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· Results of PBT and vPvB assessment
· PBT: Not applicable.
· vPvB: Not applicable.

13 Disposal considerations

· Waste treatment methods
· Recommendation Smaller quantities can be disposed of with household waste.

· Uncleaned packaging:
· Recommendation: Disposal must be made according to official regulations.

14 Transport information

· Maritime transport IMDG:
· Marine pollutant: No
· Special precautions for user Not applicable.

15 Regulatory information

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing MSDS: Product safety department
· Contact:
· Abbreviations and acronyms:
IMDG: International Maritime Code for Dangerous Goods
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

Emery Oleochemicals GmbH

Emery Oleochemicals

Safety Data Sheet according to (EC) No 1907/2006

GLYCERIN 99,5 % PF

SDS no. : 10403
Revision: 13.02.2009
printing date: 25.05.2009

1. Identification of the substance/preparation and of the company/undertaking

Trade name:
GLYCERIN 99,5 % PF

General chemical description:
Glycerol

Usage:
Oleochemical raw material

Company name:
Emery Oleochemicals GmbH
Henkelstr. 67
40551 Düsseldorf
Phone: +49 (211) 5611-2000

Contact:
sdb-oc@emeryoleo.com

Emergency information:
+49 211 797 3350

2. Hazards identification

Special hazards for man and environment according to 67/548/EC as amended
Symbols of danger:
Not subject to the regulation.
R-phrases:
none
S-phrases:
none

3. Composition / information on ingredients

General chemical description:
Glycerol

Emery Oleochemicals GmbH

Emery Oleochemicals

Safety Data Sheet according to (EC) No 1907/2006

GLYCERIN 99,5 % PF

SDS no. : 10403
Revision: 13.02.2009
printing date: 25.05.2009

4. First aid measures

General information:
In case of adverse health effects seek medical advice.
After inhalation:
not relevant.
After skin contact:
Rinse with running water.
After eye contact:
Rinse immediately with plenty of running water (for 10 minutes). Seek medical attention if necessary.
After ingestion:
Rinse the mouth. Drink 1-2 glasses of water.

5. Fire fighting measures

Suitable extinguishing media:
foam , extinguishing powder, carbon dioxide
water spray jet
Extinguishing media which must not be used for safety reasons:
None known
Special hazards by the product itself:
The product does not support combustion in any way.
None known
Additional information:
No particular measures required.

6. Accidental release measures

General information:
Danger of slipping on spilled product.
Personal precautions:
Avoid contact with skin and eyes.
Environmental precautions:
Do not empty into drains / surface water / ground water.
Process for cleaning and take-up:
Remove with liquid-absorbing material (sand, peat, sawdust).

7. Handling and storage

Handling:
Avoid open flames.

Emery Oleochemicals GmbH

Emery Oleochemicals

Safety Data Sheet according to (EC) No 1907/2006

Storage:
Store only in the original container.
Keep container tightly sealed.
Store in a cool, dry place.

8. Exposure controls / personal protection

Additional information for system design:
No particular measures required.
Respiratory protection:
Not needed.
Hand protection:
Not needed.
Eye protection:
Protective goggles
Skin protection:
suitable protective clothing
General protection and hygiene measures:
Immediately remove soiled or soaked clothing.
Do not eat, drink or smoke while working.

9. Physical and chemical properties

Designation	Value	Testing for
Delivery state:	liquid	
State:	liquid, clear	
Odor:	odorless	
Color(s):	colorless	
Boiling point	290,0 °C	no information
Melting point	18 - 22 °C	no information
Flash point	> 180,0 °C	ISO 2592
Vapor pressure (50,0 °C)	0,002500 mbar	no information
Density (20 °C)	1,2630 - 1,2651 g/cm3	PH. EUR. IV 2002: 2.2.5
Solubility (qualitative) (20 °C; Solvent: Water)	unlimited soluble	no information

10. Stability and reactivity

Materials to avoid:
None if used for intended purpose.

11. Toxicological information

Emery Oleochemicals GmbH

Emery Oleochemicals

Safety Data Sheet according to (EC) No 1907/2006

Acute oral toxicity:
LD50 > 5000 mg/kg body weight (Literature)
Skin irritation:
not irritating
Method: Draize test
Eye irritation:
not irritating
Method: OECD 405
In vitro mutagenicity:
not mutagenic
Method: Ames test

12. Ecological information

Acute fish toxicity:
LC50 > 10000 mg product/l. (Literature)
Acute invertebrate toxicity:
EC50 > 10000 mg product/l. (Literature)
Chronic bacterial toxicity:
EC0 > 10000 mg product/l.
Method: Chronic bacterial toxicity according to test method DIN 38 412 p. 8.
Aquatic plant/algae toxicity:
ErC50 > 10000 mg product/l. (Literature)
Ultimate biodegradation:
Readily and rapidly degradable. All organic substances contained in the product achieve > 60% BOD/COD or CO2 liberation, or > 70% DOC reduction in tests for ease of degradability. Threshold values for 'readily degradable' (e.g. to OECD method 301) are reached.

13. Disposal considerations

Product disposal:
Waste incineration with the approval of the responsible local authority.

14. Transport information

General information:
Not hazardous according to RID, ADR, ADNR, IMDG, IATA-DGR.

Emery Oleochemicals GmbH

Emery Oleochemicals

Safety Data Sheet according to (EC) No 1907/2006

15. Regulatory information

The labeling of the product is indicated in Section 2

National regulations/information:

WGK:	1, slightly water-endangering product. (German VwVwS of May 17, 1999, Appendix 1/2)
Storage class VCI:	10

16. Other information

Further information:
This information is based on our current level of knowledge and relates to the product in the state in which it is delivered. It is intended to describe our products from the point of view of safety requirements and is not intended to guarantee any particular properties.

CHEMI S.p.A.

SCHEDA DI SICUREZZA

Firm code: 077
Data di preparazione: 25/10/2010
Rev. N° 00
Data di stampa: 5/1/2011

	SCHEDA DI SICUREZZA	
	FERRIC PROTEIN SUCCINYLATE	Edizione : 01 Revisione: 00 Data: 25/10/2010

SEZIONE 1.
IDENTIFICAZIONE DELLA SOSTANZA E DELLA SOCIETA'/ DELL'IMPRESA

1.1. Identificatore della sostanza

Nome della sostanza:	FERRIC PROTEIN SUCCINYLATE
Altri nomi (se disponibili): Sinonimi: Denominazione Allegato VI-CLP: Denominazione Inventario delle Classificazioni ed etichettature:	4-(6-methoxy-2-naphthalenyl)-2-butanon; 4-(6-METHOXY-2-NAPHTHYL)BUTAN-2-ONE;4-[6-METHOXY-2-NAPHTHYL]-2-BUTANONE; Ironproteinsuccinylate, Ironsuccinylcasein; Non presente nell' Allegato VI-CLP Sostanze non listata nell'Inventario
Numero CAS:	93615-44-2
Nome IUPAC (se CAS non disponibile):	Non reperibile nella ricerca bibliografica effettuata
Numero di pre-registrazione REACH, opzionale	Sostanza non soggetta a registrazione REACH in virtù del suo uso
Numero di registrazione REACH, se attribuito:	Sostanza non soggetta a registrazione REACH in virtù del suo uso

1.2. Usi pertinenti identificati della sostanza e usi sconsigliati

Uso/i pertinenti:	Principio Attivo Farmaceutico
Uso/i sconsigliati:	La sostanza, è un Principio Attivo ed è indirizzata ad un uso professionale per la preparazione di specialità medicinali. Non sono previsti altri usi.

1.3. Informazioni sul fornitore della scheda dati di sicurezza

Fabbricante/Distributore: Nome Società: **CHEMI S.p.A**
Indirizzo : **Via Vadisi, 5 - 03100 Patrica (FR) – ITALY**
Telefono : **+39-0775-2581**

e-mail: fatazone@chemi.it or f.esmeraanna@chemi.com

Persona Competente per la compilazione della Scheda di Sicurezza: a.conto@chemisafe-consulting.com (Antonio Conto)

1.4. Numero telefonico di emergenza

Stabilimento: Indirizzo: **Via Vadisi, 5 - 03100 Patrica (FR) – ITALY**

N° di telefono (indicare orario di reperibilità) (ore ufficio) **+39-0775-2581**

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SEZIONE 2
IDENTIFICAZIONE DEI PERICOLI

2.1 Classificazione della sostanza

- Classificazione della sostanza secondo Regolamento (CE) n. 1272/2008:

Classe di Pericolo	Codici di Classe e di categoria di pericolo	Codici di indicazioni di pericolo	Indicazioni di pericolo
Non classificata come pericolosa	**Non previsti**	**Non previsti**	**Non previste**

- Classificazione della sostanza secondo Direttiva 67/548/CEE :

Classificazione	Simbolo di Pericolo	Frasi di Rischio
Non classificata come pericolosa	**Non previsto**	**Non previste**

Principali effetti avversi

- Effetti chimico-fisici: Non sono noti effetti chimico-fisici riconducibili a questa sostanza.
-Effetti sulla salute: Ingestione: potrebbe essere nocivo per ingestione.
Esposizione per inalazione: potrebbe essere nocivo per inalazione.
Contatto cutaneo: potrebbe essere irritante.
Contatto con gli occhi: potrebbe essere irritante.
Sensibilizzazione: dati non reperiti nella ricerca bibliografica effettuata
-Effetti sull'ambiente: Non sono noti altri pericoli per l'ambiente.
Vedi anche sezioni da 9 a 12

2.2 Elementi dell'etichetta

- Etichettatura della sostanza secondo Regolamento (CE) n. 1272/2008:

Pittogramma	**Non previsto**
Avvertenza	**Non previsto**
Indicazione di pericolo	**Non previsto**

2.3 Altri pericoli (non determinanti per la classificazione)

La sostanza soddisfa i criteri per:	SI	NO
- PBT		X
- vPvB		X

- Pericoli per l'uomo: Ingestione: bruciore di stomaco e dolori addominali.
Esposizione per inalazione: irritazione delle mucose delle vie aeree superiori.
Contatto cutaneo: arrossamento della cute.
Contatto con gli occhi : sensazione di bruciore e arrossamento della congiuntiva

- Pericoli per l'ambiente: Non sono noti altri pericoli per l'ambiente.

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- Pericoli connessi alle caratteristiche chimico-fisiche	Pericoli di fuoco ed esplosione insoliti: si presume che la sostanza sia combustibile. Come per tutte le polveri secche è consigliabile eseguire la messa a terra della strumentazione a contatto con esse al fine di dissipare il potenziale di elettricità statica. Non fumare. La sostanza emette fumi tossici in caso di incendio.
- Effetti specifici:	Non sono noti effetti specifici riconducibili a questa sostanza.

SEZIONE 3
COMPOSIZIONE / INFORMAZIONE SUGLI INGREDIENTI

Descrizione:

Nome del componente:	4-(6-methoxy-2-naphthalenyl)-2-butanon;
Concentrazione:	Sostanza pura
Formula di struttura:	Non reperibile nella ricerca bibliografica effettuata
Formula Chimica:	Non reperibile nella ricerca bibliografica effettuata
Peso Molecolare:	5.5 Milioni
Sostanza con limite comunitario:	NO
Nome CAS:	Non reperibile nella ricerca bibliografica effettuata
Numero CAS:	93165-44-2
Nome IUPAC:	Non reperibile nella ricerca bibliografica effettuata
Numero EC:	Non reperibile nella ricerca bibliografica effettuata
Index Nr.:	Non reperibile nella ricerca bibliografica effettuata
Impurezza/e (se classificate)	Non sono note impurezze. Sostanza pura.
Additivo/i (se classificati)	Non sono presenti additivi.

SEZIONE 4
MISURE DI PRIMO SOCCORSO

4.1 Descrizione delle misure di primo soccorso

- *Contatto con gli occhi:*	Lavare abbondantemente con acqua o soluzione fisiologica. Mantenere le palpebre ben sperte durante il lavaggio. Consultare il medico e mostrargli l'etichetta.
- *Contatto con la pelle:*	Rimuovere gli abiti (eventualmente le scarpe) contaminati. Lavare la parte del corpo interessata con sapone o con blando detergente e risciacquare con abbondante acqua fino alla rimozione completa della sostanza (15-20 minuti). Avvisare il medico immediatamente e mostrargli l'etichetta.
- *Ingestione:*	In caso di ingestione risciacquare la bocca abbondantemente con acqua. Avvisare il medico immediatamente e mostrargli il contenitore o l'etichetta.
- *Inalazione:*	Evitare di respirare polveri che potrebbero essere generate dal manipolare il prodotto. Spostare la persona all'aria sperta in luogo ben ventilato. Avvisare il medico se l'esposizione è stata significativa in termini di quantità o tempo.

4.2 Principali sintomi ed effetti sia acuti che ritardati

- *Sintomi ed effetti acuti:*	Ingestione: bruciore di stomaco e dolori addominali. Esposizione per inalazione: irritazione delle mucose delle vie aeree superiori. Contatto cutaneo: arrossamento della cute. Contatto con gli occhi : sensazione di bruciore e arrossamento della congiuntiva
- *Sintomi ed effetti ritardati:*	Non sono previsti sintomi ed effetti ritardati riconducibili a questa sostanza.

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4.3 Indicazione della eventuale necessità di consultare immediatamente un medico o di trattamenti speciali

- *Monitoraggio medico:* Non richiesto sulla base della classificazione della sostanza
- *Antidoti noti:* Non sono noti antidoti.
- *Controindicazioni:* Non sono note controindicazioni.
- *Trattamento specifico immediato:* Non richiesto

SEZIONE 5
MISURE ANTINCENDIO

5.1 Mezzi di estinzione

- *Mezzi di estinzione idonei:* Acqua nebulizzata, polvere chimica, schiuma , anidride carbonica
- *Mezzi di estinzione NON idonei:* Non si conoscono mezzi di estinzione non idonei

5.2 Pericoli speciali derivanti dalla sostanza

-*Prodotti di combustione pericolosi:* La decomposizione termica o la combustione possono causare la liberazione di fumi tossici e pericolosi di COx e NOx.

- *Altri pericoli speciali:* Non sono noti pericoli speciali relativi a questa sostanza.

5.3 Raccomandazioni per gli addetti all'estinzione degli incendi

vedi reg. 453/2010 pag. 10

- *Raccomandazioni tecniche di protezione:* Non cercare di estinguere il fuoco senza l'utilizzo di un apparecchio respiratorio autonomo (SCBA) e di indumenti protettivi adeguati.
- *Dispositivi di Protezione Speciale per gli addetti all'estinzione incendi:* Indossare stivali, guanti, tute, protezione occhi e volto, respiratori idonei. conformi alle pertinenti norme UNI per l'Italia e EN per l'Europa. Utilizzare i dispositivi indicati nelle massime condizioni di precauzione sulla base delle informazioni riportate nelle sottosezioni precedenti.

SEZIONE 6
MISURE IN CASO DI RILASCIO ACCIDENTALE

6.1 Precauzioni personali, dispositivi di protezione e procedure in caso di emergenza

- Equipaggiamento di protezione per chi non interviene direttamente

- *Occhi:* Indossare adeguati dispositivi di protezione (vedi sezione 8)
- *Pelle:* Indossare indumenti con protezione completa del corpo.
- *Vie aeree:* In caso di incendio e/o esplosioni evitare di respirare fumi e vapori. Utilizzare un apparecchio respiratorio autonomo (SCBA) e di indumenti protettivi adeguati. I vapori possono essere eliminati tramite nebulizzazione con acqua.

- Equipaggiamento di protezione per chi interviene direttamente

- *Occhi:* Vedi sezione 8
- *Pelle:* Vedi sezione 8
- *Vie aeree:* Vedi sezione 8

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6.2 Precauzioni ambientali

In caso di rilascio accidentale o fuoriuscita evitare che la sostanza raggiunga gli scarichi e possa raggiungere acque di superficie o sotterranee.

6.3 Metodi e materiali per il contenimento della bonifica

- *Modalità di contenimento:* Raccogliere tutto il materiale sparso al suolo con equipaggiamento protettivo adeguato e metterlo in un contenitore pulito e asciutto.
- *Modalità di bonifica:* Recuperare la sostanza per aspirazione o con altro mezzo meccanico e lavare l'area con abbondante acqua e detergenti. Stoccare il prodotto recuperato in attesa della società specializzata dello smaltimento. Se il versamento è avvenuto in autostrada o luogo pubblico, adeguati accorgimenti dovranno essere adottati al fine di proteggere le persone da qualsiasi rischio.

6.4 Riferimento ad altre sezioni

Consultare anche le sezioni 8 e 13

SEZIONE 7
MANIPOLAZIONE E IMMAGAZZINAMENTO

7.1. Precauzioni per la manipolazione sicura

- *Raccomandazioni per la manipolazione:* Manipolare lontano da fiamme e scintille
  Manipolare in locale aerato
  Evitare il contatto con materiali/sostanze incompatibili
  Indossare appropriati DPI (vedi sezione 8)
  Tenere la sostanza lontano dagli scarichi idrici
- *Raccomandazioni di igiene professionale:* Non mangiare, bere e fumare nelle zone di lavoro
  Lavare le mani dopo l'uso
  Togliere gli indumenti contaminati e i DPI prima di accedere alle zone in cui si mangia

7.2. Condizioni per l'immagazzinamento sicuro, comprese eventuali incompatibilità

Le modalità di gestione di rischi indicate in questa sezione dipende dal tipo di classificazione derivante dalle proprietà indicate nella sezione 9.
La sostanza non è classificata per alcuna proprietà chimico fisica e non si prevede alcuna modalità di gestione del rischio particolari.

Modalità di gestione dei rischi connessi a:
- *potenziali fonti di accensione:* Non esporre a fonti di calore.

Modalità di contenimento degli effetti di:
- *condizioni meteorologiche:* Stoccare il contenitore originale in luogo freddo e asciutto.
- *pressione ambientale:* Non si prevede alcuna modalità di contenimento.
- *temperature:* Stoccare in un contenitore ermeticamente chiuso in un luogo fresco e asciutto (15÷25°C) .
- *luce del sole:* Non esporre alla luce diretta del sole.
- *umidità:* Non stoccare in ambiente umido.
- *vibrazioni:* Non si prevede alcuna modalità di contenimento.

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L'applicazione delle modalità di gestione dei rischi connessi alla proprietà chimico-fisiche è da effettuare in base alle valutazioni del rischio effettuate dal datore di lavoro nella sua prassi lavorativa (uso della sostanza) in mancanza di uno scenario espositivo unico e standardizzato descritto nel Dossier di registrazione REACH.

Mantenimento dell'integrità delle sostanze:
- *stabilizzanti:* Non si prevede l'uso di stabilizzanti
- *antiossidanti:* Non si prevede l'uso di antiossidanti

Altre raccomandazioni:
- *ventilazione:* Richiesta in base allo stoccaggio della sostanza
- *progettazione specifica dei locali:* Non richiesta in base alla classificazione della sostanza
- *limiti quantitativi di stoccaggio:* Non richiesta in base alla classificazione della sostanza
- *compatibilità degli imballaggi:* Vedi punto 10.5

7.3. Usi finali specifici

- Raccomandazioni per usi finali specifici:

	SI	NO
- Scenario/i di esposizione allegato		X
- Valutazione della sicurezza chimica allegata		X
- Altre valutazioni di sicurezza disponibili (industria, di settore)		X

SEZIONE 8
CONTROLLO DELL' ESPOSIZIONE / PROTEZIONE PERSONALE

8.1. Parametri di controllo

- Valori limite di esposizione comunitari/ nazionali:	Non presenti in banche dati consultate
- Altri valori limite di esposizione comunitari/ nazionali:	Non presenti in banche dati consultate
- Valori limite biologici (BEI) comunitari/nazionali:	Non presenti in banche dati consultate
- Altre valori limite biologici (BEI) comunitari /nazionali:	Non presenti in banche dati consultate
- Procedure di monitoraggio:	La misurazione delle sostanze nell'ambiente di lavoro deve essere effettuata con metodiche standardizzate (es. UNI EN 689:1997: Atmosfera nell'ambiente di lavoro - Guida alla valutazione dell'esposizione per inalazione a composti chimici ai fini del confronto con i valori limite e strategia di misurazione; UNI EN 482:2006: Atmosfere nell'ambiente di lavoro - Requisiti generali per la prestazione di procedure per la misurazione di agenti chimici) o, in loro assenza, con metodiche appropriate
- Valori di DNEL :	La relazione sulla sicurezza chimica non è stata effettuata
- Valori di PNEC :	La relazione sulla sicurezza chimica non è stata effettuata

8.2. Controlli dell'esposizione

	SI	NO
- Scenario/i di esposizione allegato		X
- Valutazione della sicurezza chimica allegata		X

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- Conformità alle condizioni controllate di uso Solo per intermedi registrati secondo art. 17- 18		X

8.2.1. Controlli tecnici idonei

La scelta del tipo di controlli tecnici idonei è da effettuare in base alle valutazioni del rischio effettuate dal datore di lavoro nella sua prassi lavorativa (uso della sostanza) in mancanza di uno scenario espositivo unico e standardizzato descritto nel Dossier di registrazione REACH

8.2.2. Misure di protezione individuale, quali dispositivi di protezione individuale

La scelta del tipo di Dispositivo/i di Protezione Individuale (DPI) è da effettuare in base alle valutazioni del rischio effettuate dal datore di lavoro nella sua prassi lavorativa (uso della sostanza) in mancanza di uno scenario espositivo unico e standardizzato descritto nel Dossier di registrazione REACH.
Se, i risultati della valutazione dei rischi, effettuata in accordo con la direttiva 98/24/EEC (in Italia il D.Lgs. 81 del 9 Aprile 2008 e s.m.i.) dimostrano che le misure generali e collettive di prevenzione non sono sufficienti a ridurre il rischio, e qualora non si riesca a prevenire l'esposizione alla sostanza con altri mezzi, devono essere adottati adeguati dispositivi di protezione individuali, conformi alle pertinenti norme tecniche UNI/EN

a) Protezioni per occhi/volto:	Occhiali di sicurezza secondo norma EN 166; schermo facciale
b) Protezioni della pelle	
- *Protezioni delle mani:*	Guanti resistenti ai prodotti chimici secondo norma EN 374, parti 1, 2 e 3 e la direttiva comunitaria 89/686/CEE. Il materiale dei guanti deve essere impermeabile e stabile contro il prodotto/la sostanza/ la formulazione. Materiale : nitrile (gomma nitrilica), ipoallergica Spessore : non inferiore a 0.12 mm
- *Altro, protezione del corpo*	Scegliere il mezzo protettivo idoneo secondo l'attività e l'esposizione, per es. grembiule, stivali, indumenti idonei i accordo con la norma EN 14605 in caso di spruzzi o EN 13982 in caso di polveri
c) Protezione respiratoria:	Qualora la valutazione del rischio preveda la necessità di respiratori a ventilazione assistita, utilizzare un filtro antipolvere di tipo P1, P2 o P3 (EN 143). Utilizzare respiratori e componenti testati ed approvati dai competenti organismi di normazione, quali il NIOSH (USA) il CEN (UE). **La polvere è divisibile in tre categorie: 2a (polvere inerte con TLV di 10 mg/m3), 2b (sostanze nocive con TLV 0,1-10 mg/m3 (eccetto amianto)), 2c (sostanze tossiche con TLV < 0,1 mg/m3 (amianto, cancerogeni, spore, batteri, virus, semimi proteolitici). Cat. 2a: filtro P1, Cat. 2b: filtro P2, Cat.2c: filtro P3** Nelle esposizioni brevi e minime utilizzare la maschera; nelle esposizioni più intense e durature indossare l'autorespiratore
d) Pericoli termici:	Non previsti nelle prassi standard di uso della sostanza. Valutare eventuali dispositivi di protezione individuale in base a particolari condizioni di utilizzo della stessa

8.2.3 Controlli dell'esposizione ambientale

	SI	NO
- Scenario/i di esposizione allegato		X
- Valutazione della sicurezza chimica allegata		X

SEZIONE 9
PROPRIETA' FISICHE E CHIMICHE

9.1. Informazioni sulle proprietà fisiche e chimiche fondamentali

Aspetto:	Solido, polvere cristallina, bruno.

Odore:	Caratteristico, debole latte.
Soglia olfattiva:	Non reperibile nella ricerca bibliografica effettuata.
pH	2.5 - 3.5 [1]
Punto di fusione/punto di congelamento:	Non reperibile nella ricerca bibliografica effettuata
Punto di ebollizione ed intervallo di ebollizione:	Non reperibile nella ricerca bibliografica effettuata.
Punto di infiammabilità:	Non infiammabile (potrebbe essere combustibile come una qualsiasi polvere organica in miscela con l'aria).[1]
Tasso di evaporazione:	Non reperibile nella ricerca bibliografica effettuata
Infiammabilità (solidi, gas):	Non reperibile nella ricerca bibliografica effettuata.
Limiti superiore/inferiore di infiammabilità o di esplosività:	Non reperibile nella ricerca bibliografica effettuata.
Tensione di vapore:	Non reperibile nella ricerca bibliografica effettuata.
Densità di vapore:	Non reperibile nella ricerca bibliografica effettuata
Densità relativa:	Non reperibile nella ricerca bibliografica effettuata
Solubilità in acqua:	Insolubile. Solubile in soluzioni basiche.[1]
Solubilità in solventi organici:	Insolubile.[1]
Coefficiente di ripartizione ottanolo/acqua (Log Kow):	Non reperibile nella ricerca bibliografica effettuata.
Temperatura di autoaccensione:	Non reperibile nella ricerca bibliografica effettuata.
Temperatura di decomposizione:	Non reperibile nella ricerca bibliografica effettuata.
Viscosità:	Non reperibile nella ricerca bibliografica effettuata.
Proprietà esplosive:	Non reperibile nella ricerca bibliografica effettuata.
Proprietà ossidanti:	Non reperibile nella ricerca bibliografica effettuata.

9.2. Altre informazioni

Miscibilità:	Non reperibile nella ricerca bibliografica effettuata.
Liposolubilità (grasso da specificare):	Non reperibile nella ricerca bibliografica effettuata.
Conducibilità:	Non reperibile nella ricerca bibliografica effettuata
Gruppo di gas:	Non reperibile nella ricerca bibliografica effettuata
Costante di Henry (Legge di Henry):	Non reperibile nella ricerca bibliografica effettuata
Potenziale di ossido-riduzione:	Non reperibile nella ricerca bibliografica effettuata
Potenziale di formazione di radicali:	Non reperibile nella ricerca bibliografica effettuata

SEZIONE 10
STABILITA' E REATTIVITA'

10.1. Reattività

La sostanza non è considerata reattiva nelle normali condizioni d'uso.

10.2. Stabilità chimica

La sostanza è stabile nelle normali condizioni di temperatura e pressione e se conservata in contenitori chiusi in luogo fresco e ventilato. Il processo di decomposizione inizia a 300 °C. Il materiale è molto igroscopico e sensibile alla decomposizione.[1]

	NO	SI	Stabilizzante utilizzato
- Necessità di stabilizzanti:	X	-	
- Pericoli di mutamento dell'aspetto fisico	X	-	

10.3. Possibilità di reazioni pericolose

	NO	SI
- Possibilità di una reazione esotermica pericolosa:	X	-
- Possibilità di una reazione di decomposizione con aumento della pressione:	X	-
- Possibilità di degradazione con formazione di prodotti instabili:	X	-

10.4. Condizioni da evitare

Evitare l'esposizione alla luce, all'aria, all'umidità e al calore eccessivo.

10.5. Materiali incompatibili

Forti agenti ossidanti.

10.6. Prodotti di decomposizione pericolosi

La decomposizione termica o la combustione possono causare la liberazione di fumi tossici e pericolosi di COx e NOx.

SEZIONE 11
INFORMAZIONI TOSSICOLOGICHE

- Vie di esposizione:	SI	NO
- Inalazione:	X	
- Ingestione:	X	
- Contatto con la pelle:	X	
- Contatto con gli occhi:	X	

- Effetti (immediati, ritardati, cronici) **a seguito dell'esposizione** (a breve e/o lungo termine):

- *Inalazione:* Irritazione delle mucose delle vie aeree superiori.
- *Ingestione:* Bruciore di stomaco e dolori addominali.
- *Contatto con la pelle:* Arrossamento della cute
- *Contatto con gli occhi:* Sensazione di bruciore e arrossamento della congiuntiva

- Effetti tossicocinetici (Assorbimento,Distribuzione,Metabolismo,Escrezione):
Non reperibile nella ricerca bibliografica effettuata.

- *Tossicità acuta:*
- *Orale:* DL50 Orale ratto: > 4000 mg/kg [1]
  DL50 Orale topo: > 4000 mg/kg [1]
- *Dermale:* Non reperibile nella ricerca bibliografica effettuata.
- *Inalatoria:* Non reperibile nella ricerca bibliografica effettuata.
- *Altre Informazioni:* DL50 ratto intraperitoneale: 707 mg/kg [1]
  DL50 topo intraperitoneale: 707 mg/kg [1]

-Corrosione/irritazione: Non reperibile nella ricerca bibliografica effettuata

-Lesioni oculari gravi/irritazioni oculari gravi: Non sono previste lesioni gravi.

- **Sensibilizzazione:** Non reperibile nella ricerca bibliografica effettuata
- *Cutanea:* Non reperibile nella ricerca bibliografica effettuata
- *Respiratoria:* Non reperibile nella ricerca bibliografica effettuata

- Tossicità da esposizione prolungata (sperim.): Non reperibile nella ricerca bibliografica effettuata

-Effetti CMR:

- *Mutagenicità delle cellule germinali* Non reperibile nella ricerca bibliografica effettuata
- Cancerogenicità: Non reperibile nella ricerca bibliografica effettuata
- Tossicità per la riproduzione: Non reperibile nella ricerca bibliografica effettuata

Nessun dato sulle proprietà cancerogene di questa sostanza è disponibile da EPA, IARC, NTP, OSHA o ACGIH

- Tossicità specifica per organi bersaglio (STOT)-esposizione singola:
Non reperibile nella ricerca bibliografica effettuata

- Tossicità specifica per organi bersaglio (STOT)-esposizione ripetuta:
Non reperibile nella ricerca bibliografica effettuata

- Pericolo in caso di aspirazione:
Non reperibile nella ricerca bibliografica effettuata

- Ragione della mancata classificazione:
Laddove la sostanza non risulta classificata ciò è dovuto alla presenza di dati che non implicano l'applicazione della classificazione per quel determinato effetto, oppure alla mancanza di dati, oppure alla presenza di informazioni/dati inconcludenti o non sufficienti per la classificazione secondo i criteri adottati nei regolamenti citati nella presente scheda di sicurezza.

SEZIONE 12
INFORMAZIONI ECOLOGICHE

12.1. Tossicità
Non reperibile nella ricerca bibliografica effettuata

12.2. Persistenza e degradabilità
Non reperibile nella ricerca bibliografica effettuata

12.3. Potenziale di bioaccumulo
Non reperibile nella ricerca bibliografica effettuata

12.4. Mobilità nel suolo
Non reperibile nella ricerca bibliografica effettuata

12.5. Risultati della valutazione PBT e vPvB
Sulla base delle informazioni disponibili la sostanza non soddisfa i criteri per poter essere considerata un PBT o vPvB.

12.6. Altri effetti avversi
Non reperibile nella ricerca bibliografica effettuata

SEZIONE 13
CONSIDERAZIONI SULLO SMALTIMENTO

CHEMI S.p.A.

SCHEDA DI SICUREZZA

Firm code: 077
Data di preparazione: 25/10/2010
Rev. N° 00
Data di stampa: 5/1/2011

13.1. Metodi di trattamento dei rifiuti

	Incenerimento	Riciclaggio	Messa in discarica
- Rifiuti della sostanza:	X		
- Imballaggi/contenitori contaminati:	X		

Si sconsiglia lo smaltimento attraverso le acque reflue

Riferirsi alle disposizioni comunitarie/nazionali/locali in materia di smaltimento rifiuti.

SEZIONE 14
INFORMAZIONI SUL TRASPORTO

Non classificato per il trasporto in accordo con la regolamentazione RID/ADR, IMO/IMDG, ICAO/IATA.

- Trasporto di rinfuse secondo l'allegato II di Marpol 73/78 ed il codice IBC: non applicabile.

SEZIONE 15
INFORMAZIONI SULLA REGOLAMENTAZIONE

Si riportano in questa sezione le altre informazioni sulla regolamentazione della sostanza che non sono già state fornite nella scheda di sicurezza.

15.1 Norme e legislazione su salute, sicurezza e ambiente specifiche per la sostanza

- Direttiva 89/391/CEE del Consiglio, del 12 giugno 1989, concernente l'attuazione di misure volte a promuovere il miglioramento della sicurezza e della salute dei lavoratori durante il lavoro e successivi SMI e recepimenti nazionali.

- Direttiva 89/686/CEE del Consiglio, del 21 dicembre 1989, concernente il ravvicinamento delle legislazioni degli Stati membri relative ai dispositivi di protezione individuale

- Direttiva 98/24/CE del Consiglio (7 aprile 1998) "sulla protezione della salute e della sicurezza dei lavoratori contro i rischi derivanti da agenti chimici durante il lavoro (quattordicesima direttiva particolare ai sensi dell'articolo 16,, paragrafo 1, della direttiva 89/391/CEE) e successivi SMI e recepimenti nazionali.

15.2. Valutazione della sicurezza chimica

	SI	NO
- Scenario/i di esposizione allegato		X
- Valutazione della sicurezza chimica allegata		X

SEZIONE 16
ALTRE INFORMAZIONI

Revisioni:
- **Edizione n. 01 del 25/10/2010 (Prima edizione secondo l'allegato I del Regolamento 453/2010/EU)**
- **Revisione n. 00**

Fonti Bibliografiche:
[1] ChemIdplus Lite
Scheda di Sicurezza CHEMI SpA

CHEMI S.p.A.

SCHEDA DI SICUREZZA

Firm code: 077
Data di preparazione: 25/10/2010
Rev. N° 00
Data di stampa: 5/1/2011

Abbreviazioni e acronimi
- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Accordo europeo relativo al trasporto internazionale di merci pericolose su strada
- BCF: fattore di bioaccumulo
- BEI : Biological Exposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CLP: Classification, Labelling and Packaging
- CMR: (sostanze) Cancerogene, mutagene o tossiche per la riproduzione
- DPI: Dispositivi di Protezione Individuale
- EINECS: Inventario europeo delle sostanze chimiche commerciali esistenti
- EPA: US Environmental Protection Agency
- GHS: Sistema globale armonizzato per la classificazione ed etichettatura delle sostanze chimiche
- IARC: International Agency for Research on Cancer
- IATA: Codice internazionale per il trasporto aereo di merci pericolose
- IMDG: Codice internazionale per il trasporto marittimo di merci pericolose
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: livello più basso che ha determinato effetti osservabili (Lowest Observed Effect Level)
- N.A.: non applicabile
- N.D.: non disponibile
- NOAEL: dose senza effetto avverso osservabile (No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Limite di esposizione occupazionale (Occupational Exposure Limit)
- OSHA: Occupational Safety and Health Administration
- PBT: Persistenti, Bioaccumulabili e Tossiche
- RID: Accordo europeo relativo al trasporto internazionale di merci pericolose per ferrovia
- TLV/TWA: concentrazione media ponderata nel tempo, su una giornata lavorativa convenzionale di otto ore e su 40 ore lavorative settimanali
- vPvB: molto Persistente e molto Bioaccumulabile

Indicazioni sull'addestramento
Attenersi a quanto previsto dalla Direttiva 98/24/CE e successivi SMI e recepimenti nazionali.

Restrizioni d'uso raccomandate: nessuna

Sostanza in Autorizzazione : NO

AVVISO AGLI UTILIZZATORI
Questo documento ha lo scopo di fornire una guida per una manipolazione appropriata e cautelativa di questa sostanza da parte di personale qualificato o che opera sotto la supervisione di personale esperto nella manipolazione di sostanze chimiche. La sostanza non deve essere usato per scopi diversi da quelli indicati nella sezione 1, tranne nel caso in cui siano state ricevute adeguate informazioni scritte sulle modalità di manipolazione del materiale.
Il responsabile di questo documento non può fornire avvertenze su tutti i pericoli derivanti dall'uso o dall'interazione con altre sostanze chimiche o materiali. E' responsabilità dell'utilizzatore l'uso sicuro della sostanza, l'adeguatezza della sostanza all'uso per la quale viene applicata ed il corretto smaltimento. Le informazioni di seguito riportate non sono da considerarsi una dichiarazione o una

garanzia, sia espressa che implicita, di commerciabilità, di adeguatezza ad un particolare scopo, di qualità, o di qualsiasi altra natura. Le informazioni contenute in questa SDS sono conformi a quanto previsto dall'Allegato I del Regolamento n. 453/2010/EU.

BASF
The Chemical Company

Safety data sheet

BASF Safety data sheet according to 91/155/EEC
Date / Revised: 13.03.2006 Version: 1.4
Product: Kollidon® CL

(30034964/SDS_GEN_EU/EN)
Date of print 29.05.2008

1. Substance/preparation and company identification

Kollidon® CL

Use: pharmaceutical excipient

Company:
BASF SE
67056 Ludwigshafen
GERMANY
Operating Division Care Chemicals
Telephone: +49 621 60-48643
Telefax number: +49 621 60 66-48643
E-mail address: EM-Masterdata@basf.com

Emergency information:
International emergency number:
Telephone: +49 180 2273-112

2. Composition/information on ingredients

Chemical nature

polyvinylpyrrolidone, crosslinked, microgranules (MG)
CAS: 9003-39-8

3. Hazard identification

No particular hazards known.

4. First-aid measures

General advice:
Remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air.

On skin contact:
Wash thoroughly with soap and water.

On contact with eyes:
Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:
Rinse mouth and then drink plenty of water.

Note to physician:
Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-fighting measures

Suitable extinguishing media:
water spray, carbon dioxide, foam, dry extinguishing media

Specific hazards:
carbon dioxide, cyanides, nitrogen oxides
The substances/groups of substances mentioned can be released in case of fire.

Special protective equipment:
Wear a self-contained breathing apparatus.

Further information:
Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental release measures

Personal precautions:
Avoid dust formation.

Environmental precautions:
Do not discharge into drains/surface waters/groundwater.

Methods for cleaning up or taking up:
For small amounts: Sweep/shovel up.
For large amounts: Sweep/shovel up.
Dispose of absorbed material in accordance with regulations.

7. Handling and storage

Handling

Handle in accordance with good industrial hygiene and safety practice.

Protection against fire and explosion:
Avoid dust formation. The product is capable of dust explosion. Take precautionary measures against static discharges.

Storage

Further information on storage conditions: Keep container tightly closed and dry. Keep at temperature not exceeding 25 °C.

8. Exposure controls and personal protection

Personal protective equipment

Respiratory protection:
Breathing protection if breathable aerosols/dust are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1or FFP1)

Hand protection:
Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other Supplementary note: The specifications are based on own tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the determined permeation time.

Eye protection:
Safety glasses with side-shields (frame goggles) (f.e. EN 166)

Body protection:
Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures:
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Form:	powder
Colour:	white to cream colour
Odour:	faint specific odour
pH value:	approx. 3 - 7 (100 g/l, 20 °C)
melting point (decomposition):	The substance / product decomposes therefore not determined.

Ignition temperature:	approx. 440 °C	(DIN 51794)
Bulk density:	approx. 330 kg/m3	
Solubility in water:	insoluble	
Solubility (qualitative) :	insoluble	

10. Stability and reactivity

Thermal decomposition: > 145 °C

Hazardous reactions:
No hazardous reactions when stored and handled according to instructions. Dust explosion hazard.

Hazardous decomposition products:
No hazardous decomposition products if stored and handled as prescribed/indicated.

11. Toxicological information

Acute toxicity

information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
LD50 rat (oral): > 2,000 mg/kg (BASF-Test)
---

information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
LC50 rat (by inhalation): > 6.2 mg/l 4 h (OECD Guideline 403)

Irritation

information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
Primary skin irritation rabbit: non-irritant (Draize test)
---

information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
Primary irritations of the mucous membrane rabbit: non-irritant (Draize test)

Genetic toxicity

information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
No mutagenic effect was found in various tests with microorganisms and mammalian cell culture. The substance was not mutagenic in studies with mammals.
---

12. Ecological information

Ecotoxicity

Assessment of aquatic toxicity:
There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
Toxicity to fish:
LC50, 96 h, > 10,000 mg/l, Leuciscus idus, DIN 38412 Part 15, static
---

Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
Microorganisms/Effect on activated sludge:
EC20, 0.5 h, > 1,995 mg/l, activated sludge, industrial, OECD Guideline 209, aerobic
---

Persistence and degradability

Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer
Elimination information:
< 10 % DOC reduction (16 d) (OECD Guideline 302 B) (aerobic, activated sludge, industrial) Poorly eliminated from water.

Bioaccumulation potential

Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer

Based on its structural properties, the polymer is not biologically available. Accumulation in organisms is not to be expected.
---

13. Disposal considerations

Observe national and local legal requirements.

14. Transport information

Not classified as a dangerous good under transport regulations (ADR RID ADNR IMDG/GGVSee ICAO/IATA)

15. Regulatory information

Regulations of the European union (Labelling) / National legislation/Regulations

The product does not require a hazard warning label in accordance with EC Directives.

Other regulations

16. Other information

Vertical lines in the left hand margin indicate an amendment from the previous version.

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

Material Safety Data Sheet

According to regulation Nr. 1907/2006 (EU)

MEGGLE

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IDENTIFICATION

Lactose EP

1. Identification of the substance/preparation and of the company

Identification of the substance or preparation

LACTOSE Ph.Eur.:
Tablettose 70, Tablettose 80, Tablettose 100, SorboLac 400, SorboLac 400 INH, PrismaLac 40, Capsulac 60, SpheroLac 100, GranuLac 70, GranuLac 140, GranuLac 200, GranuLac 230, SacheLac 80, InhaLac 70, InhaLac 120, InhaLac 230, FlowLac 90, FlowLac 100

Use of the substance/preparation
Used for pharmaceutical formulations, food, dietetics and technical formulation.

Company/undertaking identification
Molkerei MEGGLE Wasserburg
GmbH & Co.KG
Megglestr. 6-12
D-83512 Wasserburg
Telephone ++49/8071/73-0 Telefax ++49/8071/73-444
E-Mail: sdb-info@meggle.de

Emergency Phone:
Tel.: ++49/8071/73-0 (Mo. – Th. 7:30 – 17:30 / Fr. 7:30 – 15:30 MEZ)

2. Hazards identification

2.1 Adverse human health effect(s) and symptom(s)
May cause eye irritation.
May cause skin irritation.
May cause irritation of the digestive tract. Ingestion of large amounts may cause gastrointestinal irritation.
May cause respiratory tract irritation.
Avoid formation of dust. The use of this product is described at section 8 and 7.
Substance, combustible. Dust explosive, dust explosion class: ST 1.
2.2 Adverse environmental effect(s):
Refer to section 12.

Date of issue: 23.06.2009

	Check			Approval
Date of issue	23.06.2009	23.06.2009		23.06.2009
Electronic Signature	Thomas Ranft	Eugen Schwarz		Gabriele Hueller
Date of issue				
Electronic Signature				

Material Safety Data Sheet

According to regulation Nr. 1907/2006 (EU)

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3. Composition/information on ingredients

Generic name : Lactobiose, Milksugar, Lactose Monohydrate (Ph.Eur., USP/NF, JP)
Lactose EP is a 4-O-(β-D-Galactopyranosyl)-alpha-D-glucopyranose-Monohydrate

CAS-No.: 64044-51-5	ELINCS-Index-No.:not listed
MW: 360.32 g/mol	EINECS-No.: 200-559-2
R-Phrases:	no hazardous in sence of the guideline
Content:	99 - 100 %
Molecular formula:	$C_{12}H_{22}O_{11} \cdot H_2O$

Full text of R-Phrases: refer to section 15

4. First-aid measures

4.1 On inhalation:
Move affected person into fresh air, keep warm and allow to rest. In case of accident or if the person feels unwell, seek medical advice immediately (show safety data sheet where possible).
4.2 On contact with the eyes:
On contact with the eyes, rinse immediately with plenty of water for at least 15 minutes, seek medical advice (show safety data sheet where possible).
4.3 On contact with skin:
On contact with the skin, wash off immediately with water. In case of skin reactions, seek medical advice (show safety data sheet where possible).
4.4 If swallowed:
Rinse mouth and drink 2 – 4 cupful of water
In case of accident or if you feel unwell, seek medical advice immediately (show safety data sheet where possible).

5. Fire-fighting measures

5.1 Suitable extinguishing media:
Water spray jet, Foam, ABC-powder. Co-ordinate fire-fighting measures to the fire surroundings.
5.2 Extinguishing media which must not be used for safety reasons:
unknown
5.3 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:
Substances potentially set free in case of fire: Carbon monoxide (CO), Carbon dioxide (CO_2).
5.4 Special protective equipment for firefighters:
Use breathing apparatus with independent air supply (isolated).
5.5 Additional information:
Co-ordinate fire-fighting measures to the fire surroundings. Collect contaminated firefighting water separately.

MEGGLE, Megglestr. 6–12, D-83512 Wasserburg, Tel. +49 (0) 80 71 / 73-0, Fax +49 (0) 80 71 / 73-444

Material Safety Data Sheet

MEGGLE

According to regulation Nr. 1907/2006 (EU)

6. Accidental release measures

Refer to section13. Use personal protective clothing like mentioned at section 8.
6.1 Personal precautions:
Avoid dust formation. Use personal protective clothing. Avoid eye and skin contact. Keep away sources of ignition. Don't smoke. Ensure adequate ventilation. Take precautionary measures against electrostatic loading.
6.2 Environmental precautions:
Contain spillage.
6.3 Methods for cleaning up / taking up:
Clean contaminated floors and objects thoroughly observing environmental regulations. Treat recovered material as prescribed in: Disposal considerations at section 13. Avoid dust formation. Take precautionary measures against electrostatic loading.

7. Handling and storage

7.1 Handling
Instructions for safe handling:
Refer to section 6.1
If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid contact with eyes and skin. Avoid formation of dust. If local exhaust ventilation is impossible or insufficient, provide sufficient ventilation of the workplace. Take precautionary measures against electrostatic loading. Dust explosive, dust explosion class: ST 1. Keep away from sources of ignition - refrain from smoking.
7.2 Storage
Technical measures and storage conditions:
At room temperature, in tight containers, under dry and odourless conditions.
Keep packaging tightly closed and store in a dry place.
Suitable materials for containers/equipment: common packaging for food.
Unsuitable materials for containers/equipment: no data available.
Further information on storage conditions:
Refer to section 10.2

8. Exposure controls / personal protection

8.1. Exposure limit values

Substance Name	%	Occupational exposure limits:
Dust limit		3 mg/m³ alveolar fraction 10 mg/m³ respiratory fraction

Personal protection equipment
8.1 Respiratory protection:
Respiratory protection necessary at: exposure limit excess.
Suitable respiratory protection apparatus: Particle filter (DIN EN 143, FFP1).
8.2 Hand protection:
Recommended: Disposable gloves (EN 374).
8.3 Eye protection:
Eye glasses with side protection.
8.4 Skin protection:
Protective clothing (e.g Safety shoes EN 344, long sleeved working clothes)

Additional information to hand protection: No tests were executed. The information is based on the statement of the manufacturer.

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Material Safety Data Sheet

According to regulation Nr. 1907/2006 (EU)

MEGGLE

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9. Physical and chemical properties

Appearance:	solid powder
Colour:	white
Odour:	odourless
pH-value 10%:	4.0 – 6.5 (at 100g/l water, 20 °C)
Physical state change (in °C)	Not determinable
Melting-point / Melting range:	202°C (alpha-form, monohydrate)
Flash point (in °C):	n. d. a.
Specific bulk material resistance:	1.4 x 10^13 OhmMeter for Lactose (good rechargeable product)
Flammability:	class 2-3 (*)
Explosive properties:	Dust explosive (*)
Lower explosion limit:	60 – 125 g/m³, depending on particle size (*)
Minimum ignition energy:	50 – 100 mJ, depending on particle size (*)
Minimum ignition temperature (cloud):	380 - 390°C, depending on particle size (*)
Minimum ignition temperature (layer):	~ 500°C (*)
Dust explosive class:	ST 1 (Kst. 39 – 72 bar m/s, depending on particle size) (*)
Max. explosion pressure:	5.0 – 8.5 bar, depending on particle size (*)
Vapour pressure:	n. a.

Bulk density ad	Products	Bulk density ad	Products
670-770	SorboLac 100	500-650	GranuLac 140, FlowLac 100
690-780	InhaLac 230	600-840	InhaLac 70
640-740	InhaLac 120	530-620	FlowLac 90
530-680	SachetLac 80	500-600	Tablettose 70,80,100
530-670	GranuLac 70	450-550	PrimaLac 40, GranuLac 200, 230
540-690	CapsuLac 60,	330-390	SorboLac 400/NH

Water solubility: approx. 16.1% (20 °C), freely soluble in water 53°C
Partition coefficient n-octanol /water

(*) testing of the characteristics according to VDI 2263, Bl. 1, 01. Mai 1990

10. Stability and reactivity

10.1 Conditions to avoid:
Refer to section 7. No hazardous decomposition products if stored and handled as prescribed.
Danger of dust explosion. Take precautionary measures against electrostatic loading.
10.2 Materials to avoid:
Strong smelling material
10.3 Hazardous decomposition products:
No hazardous decomposition products if stored and handled as prescribed.

11. Toxicological information

11.1 Acute toxicity:

11.1.1 LD50 Rat oral (mg/kg):	> 10g/kg. (food)
11.1.2 LD50 Rat inhalative (mg/kg/4h):	n. d. a. (food)
11.1.3 LD50 Rat dermal (mg/kg):	n. d. a. (food)
11.1.4 to eye:	n. d. a. (food)

11.2 Subacute to chronical toxicity:

11.2.1 Sensitisation:	contains traces of milk protein: inhalation of dust may lead to sensitisation in some allergic individuals (refer Section 7)
11.2.2 Carcinogenic toxic effects:	n. d. a. (food)
11.2.3 Mutagenic toxic effects:	n. d. a. (food)
11.2.4 Reproductive toxic effects:	n. d. a. (food)
11.2.5 Narcotic effects:	n. d. a. (food)

11.3 Other information:
This product contains traces of milk protein, sensitisation in some allergic individuals may be occurred.

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12. Ecological information

Water hazard class:	nwg = not water hazardous according to german VwVwS 1999 1.2d
Self-assessment:	No, KBwS
Behaviour in waste water treatment plants:	n. d. a. (food)
Aquatic toxicity:	n. d. a. (food)
Ecotoxicology:	n. d. a. (food)
Mobility:	n. d. a. (food)
Taking up an accumulation in organism:	n. d. a. (food)
(bioaccumulation potential)	n. d. a. (food)
Further ecological information:	n. d. a. (food)
Overall evaluation	product is used as food in the food industry

13. Disposal considerations

13.1 Disposal / Waste (product):
Dispose of in compliance with official regulations.
List of proposed waste codes/waste designations in accordance with EWC:

02 05 WASTES FROM THE DAIRY PRODUCTS INDUSTRY
02 05 99 wastes not otherwise specified

Landfill together with household waste, after coordination with waste management company.
13.2 Packages:
Dispose of in compliance with official regulations.
Completely emptied packages may be recycled.

14. Transport information

Land transport (ADR/GGVS, RID/GGVE)
UN-No.

Class/Packing group:	No hazardous material as defined by the transport regulations.
Classification code:	No hazardous material as defined by the transport regulations.
Label:	No hazardous material as defined by the transport regulations.

Inland waterway craft/ Marine transport (IMDG)

GGVSee/IMDG-Code:	No hazardous material as defined by the transport regulations.
EmS-No.:	No hazardous material as defined by the transport regulations.
Marine Pollutant	No hazardous material as defined by the transport regulations.

Air transport ICAO/IATA

IATA:	No hazardous material as defined by the transport regulations.

Transport / Further informations
No hazardous material as defined by the transport regulations (ADR/RID, IMDG-Code, ICAO-TI/IATA-DGR).

15. Regulatory information

Hazard(ous) symbol(s) and indication(s) of danger for dangerous substances and preparations (67/548/EEC and 1999/45/EC):
Hazard(ous) symbol(s) and indication(s) of danger

For dangerous substances and preparations:	none
R-phrases:	none
S-phrases:	none
Classification according to VbF:	n.a.
Other regulations, restrictions and prohibition regulations:	n.a.
General advices:	No hazardous material Storage class according to VCI: 11

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Material Safety Data Sheet

According to regulation Nr. 1907/2006 (EU)

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16. Other information

This information is based on our present knowledge. It characterizes the product for necessary safety precautions. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Revised sections: 9

Further information: Data references:

Legend:

n.a. = not applicable / n. d. a. = no data available

VbF = Verordnung über brennbare Flüssigkeiten

Water hazard class (WGK):

Nwgk not water hazardous, WGK1 = slightly water hazardous, WGK2 = water hazardous, WGK3 = extremely water hazardous

KEwS = Kommission Bewertung wassergefährlicher Stoffe, VwVwS = Verwaltungsvorschrift wassergefährdende Stoffe, EWC = European Waste Catalogue

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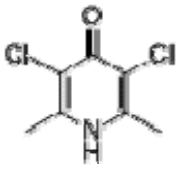
Clopidol(2971-90-6)

Clopidol Basic information

Product Name:	Clopidol
Synonyms:	3,5-dichloro-2,6-dimethyl-4-pyridino;ClopidolMeticlopidol;coccidiostatc;coyden;coyden25;methylchlorpindol;meticlorpindol;CLOPIDOL
CAS:	**2971-90-6**
MF:	C7H7Cl2NO
MW:	192.04
EINECS:	221-008-2
Product Categories:	Food and Feed Additive;Active Pharmaceutical Ingredients;Organics;Veterinaries
Mol File:	2971-90-6.mol



Clopidol Chemical Properties

mp	>320
storage temp.	0-6°C
CAS DataBase Reference	2971-90-6(CAS DataBase Reference)
EPA Substance Registry System	4-Pyridinol, 3,5-dichloro-2,6-dimethyl- (2971-90-6)

Safety Information

Hazard Codes	Xi
Risk Statements	36/37/38
Safety Statements	26
RTECS	UU7711500

MSDS Information

Clopidol Usage And Synthesis

General Description	White to light-brown, crystalline solid. Mp: 320°C. Practically insoluble in water. Administered to poultry to prevent the growth of pathogenic parasites.
Reactivity Profile	Clopidol is a non-combustible as a solid, but dust may burn rapidly or explode when mixed with air and ignited.

Clopidol Preparation Products And Raw materials

Raw materials	Dehydroacetic acid

ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : X90-519N
November 09 - P 1/4

PRODUCT : LYCASIN 80/55 - MALTITOL SYRUP acc 91/155/CEE and its amendments

01. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION:

01.1	Chemical product name	: LYCASIN 80/55 - MALTITOL SYRUP
01.2	Supplier	: ROQUETTE FRERES
	Address	: 62136 LESTREM FRANCE
	Telephone/Telefax	: 03.21.63.36.00 / 03.21.63.38.50
	Emergency telephone	: ROQUETTE FRERES FRANCE
		: 03.21.63.36.00 / 03.21.63.38.50

02. COMPOSITION/INFORMATION ON INGREDIENTS:

02.1	Substance	: yes
02.2	Common chemical name	: maltitol syrup
02.3	CAS number	: 9053-46-7
02.4	N° EINECS	: 270-337-8
02.5	Ingredients contributing to the hazard	: not applicable

03. HAZARDS IDENTIFICATION:

03.1	Most important hazards	: product delivered hot, avoid contact
03.2	Specific hazards	: not applicable
03.3	Other information	: not classified under CHIP regulation

04. FIRST-AID MEASURES:

04.1	Eye contact	: rinse with plenty of water
04.2	Skin contact	: wash with water
04.3	Ingestion	: seek medical advice according to symptoms. excessive intake may induce laxative effects depending on individual sensitivity

05. FIRE-FIGHTING MEASURES:

05.1	Extinguishing media	: water spray, foam, dry powder, carbon dioxide CO2

06. ACCIDENTAL RELEASE MEASURES:

06.1	Personal precautions	: follow recommendations for protection § 8
06.2	Environmental precautions	: generally no or weak hazard for water (biodegradable product)
06.3	Methods for cleaning up	: absorb onto inert material, and wash soiled area with plenty of water small quantities can be diluted with plenty of water and run to environmentally sound drain to eliminate residues, see § 13

07. HANDLING AND STORAGE:

07.1	Handling	
	Technical measures	: follow recommendations for personal protection § 8
	Precautions	: hot product , handle with care
	Safe handling advice	: no particular recommendations

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ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : K90-519N
November 09 - P 2/4

PRODUCT : LYCASIN 80/55 - MALTITOL SYRUP acc 91/155/CEE and its amendments

07.2 Storage	
Technical measures	: none
Storage conditions	: appropriate temperature to be maintained to avoid problems associated with increase in viscosity
Incompatible products	: strong oxidizing agent
Packaging materials	: steel drum, bulk, polythene drum, polythene container, semi bulk container

08. EXPOSURE CONTROLS/PERSONAL PROTECTION:

08.1 Personal protective equipment	
Respiratory protection	: not necessary
Eye protection	: not necessary
Hand protection	: not necessary
Skin and body protection	: not necessary
08.2 Hygiene measures	: general hygiene practices for chemical products handling

09. PHYSICAL AND CHEMICAL PROPERTIES:

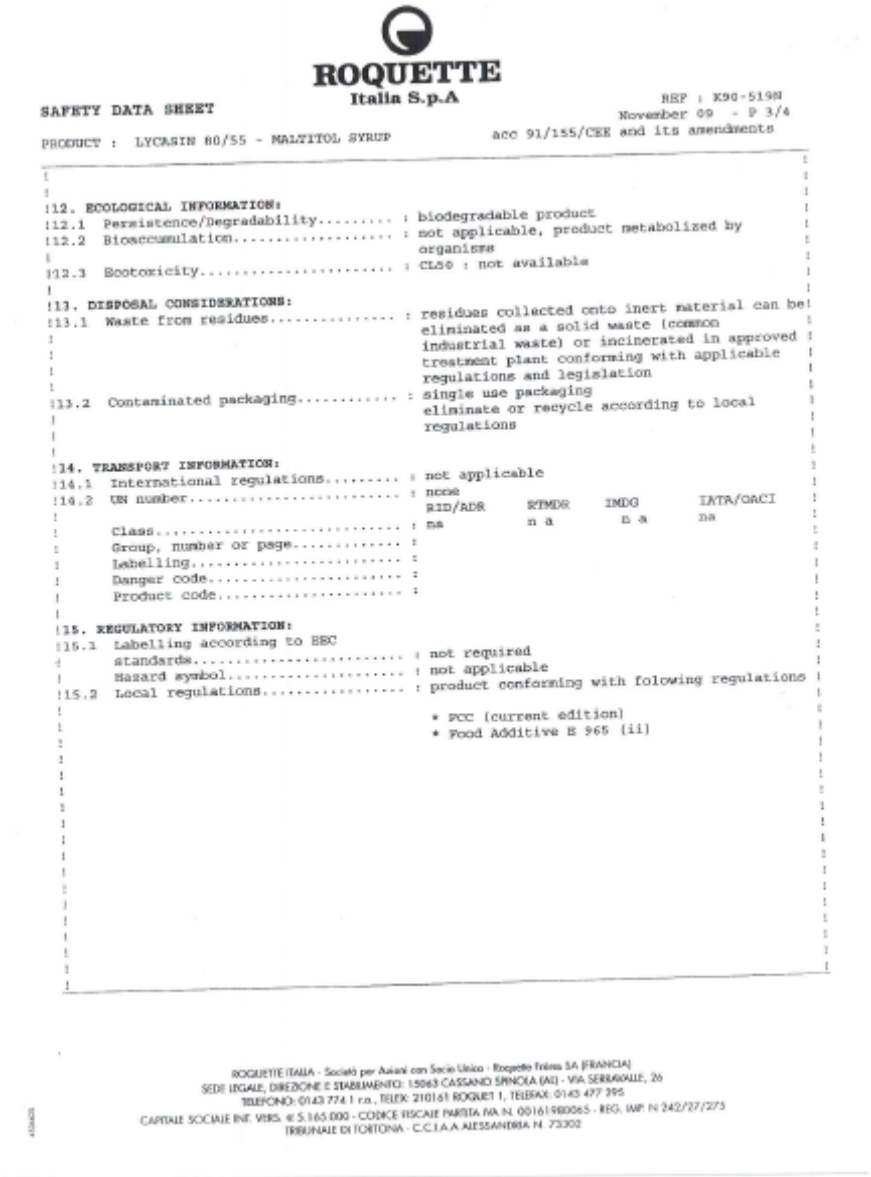
09.1 Physical state	: syrupy liquid
Colour	: colourless
Odour	: odourless
09.2 pH (concentration)	: 5.0 - 7.0 at 50 %
09.3 Boiling temperature	: > 100 ° C
Melting point	: not applicable
Flashpoint	: not applicable
09.4 Explosion properties	: not applicable, water based liquid
09.5 Vapour pressure	: 17 mm Hg (water)
09.6 Vapour density	: approx 0.7 (water)
09.7 Density	: approx 1.44
09.8 Solubility	: totally soluble
09.9 Other data	: viscosity at 10 °C : approx 7500 mPa.s

10. STABILITY AND REACTIVITY:

10.1 Stability	: stable with respect to storage conditions § 7
10.2 Hazardous reactions	: not concerned
10.3 Conditions to avoid	: product with tendency to increase in viscosity at low temperature
10.4 Materials to avoid	: strong oxidizing agents
10.5 Hazardous decomposition products	: typical decomposition products : Carbon monoxide and dioxide, water, oxygen

11. TOXICOLOGICAL INFORMATION:

11.1 Acute toxicity	: DL50 : not available
11.2 Local effects	: not applicable
11.3 Other information	: no known toxicity



ROQUETTE
Italia S.p.A

SAFETY DATA SHEET

REF : K90-519N
November 09 - P 3/4

PRODUCT : LYCASIN 80/55 - MALTITOL SYRUP

acc 91/155/CEE and its amendments

12. ECOLOGICAL INFORMATION:

12.1 Persistence/Degradability..... : biodegradable product

12.2 Bioaccumulation..... : not applicable, product metabolized by organisms

12.3 Ecotoxicity..... : CL50 : not available

13. DISPOSAL CONSIDERATIONS:

13.1 Waste from residues..... : residues collected onto inert material can be eliminated as a solid waste (common industrial waste) or incinerated in approved treatment plant conforming with applicable regulations and legislation

13.2 Contaminated packaging..... : single use packaging
eliminate or recycle according to local regulations

14. TRANSPORT INFORMATION:

14.1 International regulations..... : not applicable

14.2 UN number..... : none

	RID/ADR	RTMDR	IMDG	IATA/OACI
Class.....	na	n a	n a	na
Group, number or page.....				
Labelling.....				
Danger code.....				
Product code.....				

15. REGULATORY INFORMATION:

15.1 Labelling according to EEC standards..... : not required

Hazard symbol..... : not applicable

15.2 Local regulations..... : product conforming with folowing regulations

* FCC (current edition)
* Food Additive E 965 (ii)

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ROQUETTE
Italia S.p.A

SAFETY DATA SHEET

REF : K90-519N
November 09 - P 4/4

PRODUCT : LYCASIN 80/55 - MALTITOL SYRUP

Acc 91/155/CEE and its amendments

16. OTHER INFORMATION:

Note :
This bulletin completes the Technical Directions for use but is not a substitute for them.
Attention is drawn to the risks encountered when the product is used in applications other than those for which intended.
It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.
All information and instructions provided in this Safety Data Sheet (SDS) is made with no warranty ; they are based on the current state of our knowledge at the latest revision date indicated.
* Updating :
The modified texts of the former versions are marked with an asterisk (*).

Lestrem, 9 May 2011

Quality Assurance

ROQUETTE ITALIA - Società per Azioni con Socio Unico - Roquette Frères SA (FRANCIA)
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ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : K50-106K
November 05 - P 1/4

PRODUCT : LYCATAB PGS acc 91/155/CEE and its amendments

01. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION:

01.1	Chemical product name	: LYCATAB PGS
01.2	Supplier	: ROQUETTE FRERES
	Address	: 62136 LESTREM FRANCE
	Telephone/Telefax	: 03.21.63.36.00 / 03.21.63.38.50
	Emergency telephone	: ROQUETTE FRERES FRANCE
		: 03.21.63.36.00 / 03.21.63.38.50

02. COMPOSITION/INFORMATION ON INGREDIENTS:

02.1	Substance	: yes
02.2	Common chemical name	: cold water soluble maize starch
02.3	CAS number	: 9005-25-8
02.4	N° EINECS	: 232-679-6
02.5	Ingredients contributing to the hazard	: not applicable

03. HAZARDS IDENTIFICATION:

03.1	Most important hazards	: potential for formation of explosive air / dust cloud
03.2	Specific hazards	: explosion hazards, see § 3.1
03.3	Other information	: not classified under CHIP regulation

04. FIRST-AID MEASURES:

04.1	Inhalation	: remove to fresh air ; if symptoms develop, seek medical advice
04.2	Eye contact	: rinse with plenty of water, seek medical attention
04.3	Skin contact	: wash with water and soap
04.4	Ingestion	: seek medical attention according to symptoms

05. FIRE-FIGHTING MEASURES:

05.1	Extinguishing media	: water spray
05.2	Non-suitable extinguishing media	: CO2 : inactive Powder : hazards of dust cloud formation

06. ACCIDENTAL RELEASE MEASURES:

06.1	Personal precautions	: follow recommendations for protection § 8
06.2	Environmental precautions	: generally no or weak hazard for water (biodegradable product)
06.3	Methods for cleaning up	: collect mechanically, vacuum up, if necessary wash with water; the product becomes slippery when rewet to eliminate residues , see § 13

07. HANDLING AND STORAGE:

07.1	Handling Technical measures	: follow recommendations for personal protection § 8

ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : K50-106E
November 05 - P 2/4
PRODUCT : LYCATAB PGS acc 91/155/CEE and its amendments

		Premises where dust can be generated must be identified per areas and equipped according to the ATEX directive. (*)
	Precautions	: avoid dust formation or dispersion in the air
	Safe handling advice	: follow general recommendations for handling of dusty products Any handling and/or storage of products must be suited to the explosibility characteristics of each product, which are well known by the customer. He is the sole responsible person and must therefore take action to avoid any accident hazard (explosion in particular) and/or product alteration. (*)
07.2	Storage	
	Technical measures	: Bulk storage silos must be compliance with the ATEX directive. (*)
	Storage conditions	: store in a cool and dry area
	Incompatible products	: strong oxidizing agents
	Packaging materials	: polythen and paper bag
08.	EXPOSURE CONTROLS/PERSONAL PROTECTION:	
08.1	Control parameters	: follow the national regulation applicable to non specific total dusts AEL <= 10 mg/m3 (France)
08.2	Personal protective equipment	
	Respiratory protection	: dust mask in case of dust occurence
	Eye protection	: appropriate goggles (optional)
	Hand protection	: not necessary
	Skin and body protection	: none
08.3	Hygiene measures	: general hygiene practices for chemical products handling
09.	PHYSICAL AND CHEMICAL PROPERTIES:	
09.1	Physical state	: powder
	Colour	: off-white
	Odour	: neutral
09.2	pH (concentration)	: 5.0 - 7.0 at 3 %
09.3	Boiling temperature	: not applicable
	Flashpoint	: not applicable
	Autoignition temperature	: 520 °C (GG - cloud)
09.4	Explosion properties	: min ignition energy : approx > 1200 mJ max explosion pressure : approx 7.6 bars KST : approx 85 bar m/s Class (VDI 3673 ST) : 1 min explosible concentration : 30 - 60 g/m3 (ref : INERIS, similar to Pregeflo M)
09.5	Density	: approx 0.50 kg/l
09.6	Solubility	: soluble at 20 °C (approx 150 g/l)

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ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : K50-106K
November 05 - P 3/4

PRODUCT : LYCATAB PGS acc 91/155/CEE and its amendments

10. STABILITY AND REACTIVITY:

10.1	Stability	: stable with respect to storage conditions §7
10.2	Hazardous reactions	: air / dust mixture (explosion hazards)
10.3	Materials to avoid	: strong oxidizing agents
10.4	Hazardous decomposition products	: typical decomposition products : Carbon monoxide and dioxide, oxygen, water

11. TOXICOLOGICAL INFORMATION:

11.1	Acute toxicity	: DL50 : not available
11.2	Local effects	: rubbing may cause mechanical skin irritation for hypersensitive individuals
11.3	Other information	: no known toxicity

12. ECOLOGICAL INFORMATION:

12.1	Persistence/Degradability	: biodegradable product
12.2	Bioaccumulation	: not applicable, product metabolized by organisms
12.3	Bootoxicity	: CL50 : not available

13. DISPOSAL CONSIDERATIONS:

13.1	Waste from residues	: can be eliminated as a solid waste (common industrial waste) or incinerated in approved treatment plant conforming with applicable regulations and legislation
13.2	Contaminated packaging	: single use packaging eliminate or recycle according to local regulations

14. TRANSPORT INFORMATION:

14.1	International regulations	: not applicable
14.2	UN number	: none

	RID/ADR	RTMDR	IMDG	IATA/OACI
Class	n a	n a	n a	n a
Group, number or page				
Labelling				
Danger code				
Product code				

15. REGULATORY INFORMATION:

15.1	Labelling according to EEC standards	: not required
	Hazard symbol	: not applicable

16. OTHER INFORMATION:

Note :

ROQUETTE
Italia S.p.A

SAFETY DATA SHEET REF : K50-106X
November 05 - P 4/4

PRODUCT : LYCATAB PGS acc 91/155/CEE and its amendments

This bulletin completes the Technical Directions for use but is not a substitute for them.
Attention is drawn to the risks encountered when the product is used in applications other than those for which intended.
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* Updating :
The modified texts of the former versions are marked with an asterisk (*).

Quality Assurance Lestrem, 9 May 2011