



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** BEECHAMS CAPLETS

### Other means of identification

#### Synonyms

BEECHAMS FLU PLUS CAPLETS \* BEECHAMS ACTIVE COLD RELIEF CAPLETS \*  
PARACETAMOL 500 MG, CAFFEINE 25 MG AND PHENYLEPHRINE HYDROCHLORIDE 5 MG  
CAPLETS \* PARACETAMOL, CAFFEINE AND PHENYLEPHRINE HYDROCHLORIDE,  
FORMULATED PRODUCT

### Recommended use of the chemical and restrictions on use

**Recommended use** Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Restrictions on use** No other uses are advised.

### Details of manufacturer or importer

#### Manufacturer

GlaxoSmithKline Australia  
1061 Mountain Highway  
Melbourne, Victoria 3155  
Australia  
Australia General Information (Normal Business Hours): (03) 9721 6000

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TRANSPORTATION EMERGENCY NUMBERS  
(available 24hrs/7days: multi-language response)  
Australia Toll Free +(61) 2 9037 2994  
International Toll Call +(1) 703 527 3887

## 2. Hazard(s) identification

### Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
PARACETAMOL	103-90-2	< 75
ACETAMIDE, N-(4-HYDROXYPHENYL)- ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PANADOL PARACETAMOL TYLENOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE		

ALPHA-AMYLODEXTRIN AMYLODEXTRIN AMYLOGEN SOLUBLE STARCH THYODENE STARCH SOLUBLE OHS40192	9005-84-9	3 - < 5
MICROCRYSTALLINE CELLULOSE AVICEL PH MICROCRYSTALLINE CELLULOSE ABICEL ALPHA-CELLULOSE ARBOCEL ARBOCELL B 600/30 ARBOCELL BC 200 AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 BETA-AMYLOSE CELLEX MX CELLULOSE (8CI9CI) CELLULOSE 248 CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELUFI CRYSTALLINE CELLULOSE EMOCEL MCC MICROCRYSTALLINE CELLULOSE POWDERED CELLULOSE RTECS FJ5691460 SOLKA FLOC BW200 CELLULOSA (FIBRA PAPEL) CELLULOSE (PAPER FIBRES) CELLULOSE-PAPER FIBER CELULOSA (FIBRA PAPEL) TSELLULOOS	9004-34-6	3 - < 5
PREGELATINIZED STARCH	9005-25-8	3 - < 5
L-ASCORBIC ACID VITAMIN C	50-81-7	< 7.5
CAFFEINE TRIMETHYLXANTHINE METHYLTHEOBROMINE CAFFEINE ANHYDROUS	58-08-2	< 5
Starch ARROWROOT STARCH CORN STARCH POTATO STARCH RICE STARCH	9005-25-8	< 5
Talc TALCUM, NON-ASBESTOS FORM Talc HYDROUS MAGNESIUM SILICATE	14807-96-6	< 5

HYDROXYPROPYL METHYL CELLULOSE METHOCEL K4M GONIOSOL ISOPRO ALKALINE METHOCEL E,F,K METHOCEL HG METHYL CELLULOSE PROPYLENE GLYCOL ETHER HYPROMELLOSE CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER METHYLHYDROXYPROPYLCELLULOSE PHARMACOAT 603	9004-65-3	1 - < 3
MAIZE STARCH STARCH, EDIBLE STARCH (CORN)	9005-25-8	1 - < 3
MASTERCOTE FA 1202		< 1
PHENYLEPHRINE HYDROCHLORIDE (-)-M-HYDROXY-ALPHA-((METHYLAMINO)METHYL)BENZYL ALCOHOL HYDROCHLORIDE ISOPHRIN HYDROCHLORIDE LEVOPHENYLEPHRINE HYDROCHLORIDE METAOXEDRINE HYDROCHLORIDE META-SYNEPHRINE HYDROCHLORIDE NEOPHRYN NEO-SYNEPHRINE HYDROCHLORIDE L-PHENYLEPHRINE HYDROCHLORIDE BENZENEMETHANOL, 3-HYDROXY-ALPHA-(METHYLAMINO)METHYL-), HYDROCHLORIDE, (R)-	61-76-7	< = 1
Polyvinylpyrrolidone 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER POLY(N-VINYLPYRROLIDONE) PLASDONE	9003-39-8	< 1
Stearic acid 1-HEPTADECANECARBOXYLIC ACID Octadecanoic acid STEAROPHANIC ACID N-OCTADECANOIC ACID C18H36O2 OHS21873 RTECS WI2800000	57-11-4	< 1
DODECYL SODIUM SULFATE DODECYL SULFATE, SODIUM SALT SODIUM LAURYL SULPHATE LAURYL SULFATE SODIUM SALT	151-21-3	< 0.2
Polyethylene glycol AZIRIDINE, HOMOPOLYMER, ETHOXYLATED OHS19172	68130-99-4	< 0.2

Propylene glycol	57-55-6	< 0.2
1,2-Propanediol		
1,2-DIHYDROXYPROPANE		
2-HYDROXYPROPANOL		
ISOPROPYLENE GLYCOL		
METHYLETHYLENE GLYCOL		
METHYLETHYL GLYCOL		
MONOPROPYLENE GLYCOL		
2,3-PROPANEDIOL		
ALPHA-PROPYLENE GLYCOL		
1,2-PROPYLENE GLYCOL		
(RS)-1,2-PROPANEDIOL		
1,2-(RS)-PROPANEDIOL		
1,2-PROPANDIOL		
DL-1,2-PROPANEDIOL		
DL-PROPYLENE GLYCOL		
PROPANE-1,2-DIOL (PROPYLENE GLYCOL)		
PROPANE-1-2-DIOL		
PROPANEDIOL,1,2-		
ETHYLCELLULOSE	9004-57-3	< 0.1
ETHYL ETHER CELLULOSE		
CELLULOSE ETHYLATE		
CELLULOSE ETHYL		
ETHOCEL		
CELLULOSE, ETHYL ETHER		
ETHYL CELLULOSE ETHER		
ETHYL CELLULOSE		
OHS08875		
RTECS FJ5950500		

FD & C YELLOW #6

2783-94-0

< 0.1

2-NAPHTHALENESULFONIC ACID,  
6-HYDROXY-5-((4-SULFOPHENYL)AZO)-, DISODIUM SALT  
DISODIUM  
6-HYDROXY-5-((4-SULPHONATOPHENYL)AZO)NAPHTHALENE-2-SULPHO  
NATE DISODIUM  
6-HYDROXY-5-((4-SULFONATOPHENYL)AZO)NAPHTHALENE  
2-SULFONATE  
6-HYDROXY-5-((4-SULFOPHENYL)AZO)-2-NAPHTHALENESULFONIC  
ACID DISODIUM SALT  
6-HYDROXY-5-((PARA-SULFOPHENYL)AZO)-2-NAPHTHALENESULFONIC  
ACID DISODIUM SALT  
6-HYDROXY-5-((P-SULFOPHENYL)AZO)-2-NAPHTHALENESULFONIC  
ACID DISODIUM SALT  
1-PARA-SULFOPHENYLAZO-2-HYDROXYNAPHTHALENE-6-SULFONATE,  
DISODIUM SALT  
1-P-SULFOPHENYLAZO-2-HYDROXYNAPHTHALENE-6-SULFONATE,  
DISODIUM SALT  
1-PARA-SULFOPHENYLAZO-2-NAPHTHOL-6-SULFONIC ACID, DISODIUM  
SALT  
1-P-SULFOPHENYLAZO-2-NAPHTHOL-6-SULFONIC ACID, DISODIUM SAL  
T  
1-PARA-SULFOPHENYLAZO-2-NAPHTHOL-6-SULFONIC ACID DISODIUM  
SALT  
1-P-SULFOPHENYLAZO-2-NAPHTHOL-6-SULFONIC ACID DISODIUM SALT  
1-PARA-SULPHOPHENYLAZO-2-NAPHTHOL-6-SULPHONIC ACID,  
DISODIUM SALT  
1-P-SULPHOPHENYLAZO-2-NAPHTHOL-6-SULPHONIC ACID, DISODIUM  
SALT  
C.I. 15985  
C.I. FOOD YELLOW 3, DISODIUM SALT  
C.I. FOOD YELLOW 3  
FD AND C YELLOW 6  
D AND C YELLOW NO. 6  
FD&C YELLOW 6  
FD AND C YELLOW NO. 6  
ACID FOOD YELLOW 3  
FOOD YELLOW 3  
FOOD YELLOW 5  
FOOD YELLOW 6  
1351 YELLOW  
1899 YELLOW  
NO. 8002 FD & C YELLOW #6 GRANULES  
FOOD YELLOW NO. 5  
ACID YELLOW TRA  
SUNSET YELLOW FCF  
SUNSET YELLOW 3  
C16H10N2Na2O7S2  
OHS09671  
RTECS QK2450000

POTASSIUM SORBATE

24634-61-5

< 0.1

SORBIC ACID, POTASSIUM SALT  
SORBISTAT-K  
SORBISTAT-POTASSIUM  
2,4-HEXADIENOIC ACID, POTASSIUM SALT, (E,E)-  
(E,E)-2,4-HEXADIENOIC ACID, POTASSIUM SALT  
POTASSIUM-2,4-HEXADIENOATE

< 15

## 4. First-aid measures

### Description of necessary first aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without medical advice.
<b>Personal protection for first-aid responders</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>Symptoms caused by exposure</b>	None known.
<b>Medical attention and special treatment</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

## 5. Fire-fighting measures

<b>Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for fire fighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Hazchem Code</b>	Not available.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
<b>Environmental precautions</b>	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimise dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
<b>Conditions for safe storage, including any incompatibilities</b>	Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls and personal protection

<b>Control parameters</b>	Follow standard monitoring procedures.
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## Occupational exposure limits

### GSK

Components	Type	Value
CAFFEINE (CAS 58-08-2)	8 HR TWA	200 mcg/m <sup>3</sup>
	OHC	2
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1
L-ASCORBIC ACID (CAS 50-81-7)	8 HR TWA	5000 mcg/m <sup>3</sup>
	OHC	1
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m <sup>3</sup>
	OHC	1
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	15 MIN STEL	200 mcg/m <sup>3</sup>
	8 HR TWA	30 mcg/m <sup>3</sup>
	OHC	3

### Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Inhalable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>	Inhalable fibers.
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Inhalable dust.
Starch (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Inhalable dust.
Stearic acid (CAS 57-11-4)	TWA	10 mg/m <sup>3</sup>	Inhalable dust.
Talc (CAS 14807-96-6)	TWA	2.5 mg/m <sup>3</sup>	

### Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Inspirable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>	Inspirable dust.
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Inspirable dust.
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m <sup>3</sup>	Total vapour and particulates.
		10 mg/m <sup>3</sup>	Particulate.
		150 ppm	Total vapour and particulates.
Starch (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	Inspirable dust.
Stearic acid (CAS 57-11-4)	TWA	10 mg/m <sup>3</sup>	Inspirable dust.
Talc (CAS 14807-96-6)	TWA	2.5 mg/m <sup>3</sup>	

### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>	

**US. ACGIH Threshold Limit Values**

Components	Type	Value	Form
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	
Starch (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	
Stearic acid (CAS 57-11-4)	TWA	10 mg/m <sup>3</sup>	
Talc (CAS 14807-96-6)	TWA	2 mg/m <sup>3</sup>	Respirable fraction.

**UK. EH40 Workplace Exposure Limits (WELs)**

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	4 mg/m <sup>3</sup>	Respirable.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	10 mg/m <sup>3</sup> 20 mg/m <sup>3</sup>	Inhalable Inhalable dust.
PARACETAMOL (CAS 103-90-2)	TWA	4 mg/m <sup>3</sup> 10 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>	Respirable dust. Inhalable dust. Inhalable dust.
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	4 mg/m <sup>3</sup>	Respirable.
Propylene glycol (CAS 57-55-6)	TWA	10 mg/m <sup>3</sup> 474 mg/m <sup>3</sup> 10 mg/m <sup>3</sup> 150 ppm	Inhalable Total vapour and particulates. Particulate. Total vapour and particulates.
Starch (CAS 9005-25-8)	TWA	4 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>	Respirable. Inhalable
Talc (CAS 14807-96-6)	TWA	1 mg/m <sup>3</sup>	Respirable dust.

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

General ventilation normally adequate. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

**Individual protection measures, for example personal protective equipment (PPE)****Eye/face protection**

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

**Skin protection****Hand protection**

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

**Other**

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

**9. Physical and chemical properties****Appearance****Physical state**

Solid.

**Form**

Caplet.

**Colour**

Not available.

**Odour**

Not available.

**Odour threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.



<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
<b>Incompatible materials</b>	Alkali metals.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Ingestion</b>	Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Symptoms related to exposure** None known.

**Acute toxicity** Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

<b>Components</b>	<b>Species</b>	<b>Test results</b>
CAFFEINE (CAS 58-08-2)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rat	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	192 mg/kg

Components	Species	Test results
<b>Subchronic</b>		
<i>Oral</i>		
NOAEL	Mouse	167 - 179 mg/kg/day Dosed in drinking water - Continuous
	Rat	151 - 174 mg/kg/day Dosed in drinking water - Continuous
DODECYL SODIUM SULFATE (CAS 151-21-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1288 mg/kg
ETHYLCELLULOSE (CAS 9004-57-3)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 5000 mg/kg
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
L-ASCORBIC ACID (CAS 50-81-7)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	11.9 g/kg
<b>Subchronic</b>		
<i>Oral</i>		
NOAEL	Rat	2000 mg/kg/day
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
<b>Subacute</b>		
<i>Oral</i>		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
<b>Subchronic</b>		
<i>Oral</i>		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
<i>Other</i>		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous

Components	Species	Test results
TD	Mouse	6100 ppm, 13 weeks dietary, continuous 1.25 %, 41 weeks dietary, continuous
<b>PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)</b>		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	350 mg/kg
<b>Subacute</b>		
<i>Oral</i>		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
<b>Subchronic</b>		
<i>Oral</i>		
LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study
	Rat	5000 - 20000 ppm, 12 weeks dietary study
LOAEL	Mouse	1250 ppm, 12 weeks dietary study
	Rat	1250 ppm, 12 weeks dietary study
<b>Polyvinylpyrrolidone (CAS 9003-39-8)</b>		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
<b>POTASSIUM SORBATE (CAS 24634-61-5)</b>		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	4340 mg/kg
<b>Stearic acid (CAS 57-11-4)</b>		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
* Estimates for product may be based on additional component data not shown.		
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.	
<b>Irritation Corrosion - Skin</b>		
L-ASCORBIC ACID	Acute dermal irritation; OECD 404 Result: Non-irritant Species: Rabbit Notes: EU SCC Review 1986-1990	
CAFFEINE	Literature data Result: Non-irritant Species: Rabbit	
PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Non-irritant Species: Rabbit Notes: US Pharmacopeia	
<b>Irritation Corrosion - Skin: P.I.I. value</b>		
PARACETAMOL	OECD 404, Literature data Result: Slight irritant Species: Rabbit	
<b>Serious eye damage/irritation</b>	Health injuries are not known or expected under normal use.	
<b>Eye</b>		
L-ASCORBIC ACID	Acute ocular irritation; OECD 405 Result: Slight irritant Species: Rabbit Notes: EU SCC Review 1986-1990	

**Eye**

PHENYLEPHRINE HYDROCHLORIDE

Clinical use  
Result: Pharmacological, cardiovascular effects.  
Species: Human

CAFFEINE

Literature data  
Result: Not likely to be a severe irritant  
Species: Rabbit

PARACETAMOL

OECD 405  
Result: Slight irritant  
Species: Rabbit

PHENYLEPHRINE HYDROCHLORIDE

Supplier SDS  
Result: Irritant**Eye / Initial pain reaction score**

PARACETAMOL

Literature data

**Respiratory or skin sensitisation****Skin sensitisation**

This product is not expected to cause skin sensitisation.

**Maximisation assay (Magnusson and Kligman)**

HYDROXYPROPYL METHYL CELLULOSE

Result: negative  
Species: Guinea pig**Sensitisation**

PHENYLEPHRINE HYDROCHLORIDE

Clinical use - Ophthalmology  
Result: Low incidence of contact hypersensitivity.  
Species: Human

CAFFEINE

Literature data  
Result: negative  
Species: Mouse**Germ cell mutagenicity**

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**

CAFFEINE

25 - 100 mg/kg Chromosomal Aberration Assay In Vivo  
Result: positive  
Species: Mouse

PHENYLEPHRINE HYDROCHLORIDE

25 - 100 mg/kg Micronucleus Assay  
Result: negative  
Species: Mouse

PARACETAMOL

Ames  
Result: negative

CAFFEINE

Ames  
Result: negative  
Notes: NTP Study report - Phenylephrine.

PHENYLEPHRINE HYDROCHLORIDE

Ames, Literature data  
Result: negative

PARACETAMOL

Chromosomal Aberration Assay In Vitro  
Result: positive

CAFFEINE

Chromosomal Aberration Assay In Vitro, CHO cells  
Result: negative

PARACETAMOL

Notes: NTP Study report - Phenylephrine.  
Chromosomal Aberration Assay In Vitro, Literature data  
Result: positive

PHENYLEPHRINE HYDROCHLORIDE

HPRT gene mutation in human lymphocytes, Literature data  
Result: negative

CAFFEINE

In vivo Micronucleus  
Result: positive

PARACETAMOL

In vivo Micronucleus, Literature data  
Result: negative

PHENYLEPHRINE HYDROCHLORIDE

Species: Mouse  
L5178Y mouse lymphoma thymidine kinase locus assay  
Result: Equivocal

CAFFEINE

Notes: NTP Study report - Phenylephrine.  
L5178Y mouse lymphoma thymidine kinase locus assay  
Result: positive

PHENYLEPHRINE HYDROCHLORIDE

sister chromatid exchange  
Result: positive  
Notes: NTP Study report - Phenylephrine.

**Carcinogenicity**

Health injuries are not known or expected under normal use. Contains a material (talc) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

CAFFEINE	0.1 - 0.2 %, Dosed in drinking water Result: negative Species: Rat Test Duration: 78 weeks
L-ASCORBIC ACID	1000 - 2000 mg/kg/day Result: negative Species: Rat Notes: UN SIDS Dossier
PHENYLEPHRINE HYDROCHLORIDE	133 - 270 mg/kg/day Result: negative Species: Mouse Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.
CAFFEINE	200 - 2000 mg/l, Dosed in drinking water Result: negative Species: Rat Test Duration: 2 years
PHENYLEPHRINE HYDROCHLORIDE	24 - 50 mg/kg/day Result: negative Species: Rat Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.
L-ASCORBIC ACID	< 6000 mg/kg/day Result: negative Species: Mouse Notes: UN SIDS Dossier
PARACETAMOL	Literature data Result: Equivocal. Increase in adenomas at toxic dose. Species: Mouse Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat Literature data Result: negative Species: Mouse Literature data Result: negative Species: Rat

**ACGIH Carcinogens**

MAIZE STARCH (CAS 9005-25-8)	A4 Not classifiable as a human carcinogen.
PREGELATINIZED STARCH (CAS 9005-25-8)	A4 Not classifiable as a human carcinogen.
STARCH (CAS 9005-25-8)	A4 Not classifiable as a human carcinogen.
STEARIC ACID (CAS 57-11-4)	A4 Not classifiable as a human carcinogen.
TALC (CAS 14807-96-6)	A4 Not classifiable as a human carcinogen.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

CAFFEINE (CAS 58-08-2)	3 Not classifiable as to carcinogenicity to humans.
FD & C YELLOW #6 (CAS 2783-94-0)	3 Not classifiable as to carcinogenicity to humans.
PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
POLYVINYLPIRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TALC (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity**

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

**Specific target organ toxicity - single exposure**

Causes damage to organs.

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Organ: Cardiovascular effects, some marked.
CAFFEINE	Literature data Organ: Nervous system; Cardiovascular system

**Specific target organ toxicity - single exposure**

PARACETAMOL

Species: Human  
Organ: Liver**Specific target organ toxicity - repeated exposure**

L-ASCORBIC ACID

May cause damage to organs through prolonged or repeated exposure by ingestion.

Species: Human  
Organ: Red blood cells, kidneys.  
Notes: EU SCC Review 1986-1990**Aspiration hazard**

Not likely, due to the form of the product.

**Other information**

Caution - Pharmaceutical agent.

**12. Ecological information****Ecotoxicity**

The product contains a substance which may cause long-term adverse effects in the environment.

**Components****Species****Test results**

## CAFFEINE (CAS 58-08-2)

**Aquatic***Acute*Activated Sludge  
Respiration

IC50

Residential sludge

&gt; 1000 mg/l, 3 hours Nominal, OECD 209

NOEC

Residential sludge

1000

Algae

EC50

Green algae (Desmodesmus subspicatus)

&gt; 100 mg/l, 72 hours OECD 201

Green algae (Scenedesmus subspicatus)

&gt; 100 mg/l, 72 hours Measured, OECD 201

NOEC

Algae

100 mg/l

Crustacea

EC50

Water flea (Daphnia magna)

182 mg/l, 48 hours German std DIN 38412

Fish

LC50

Fathead minnow (Adult Pimephales promelas)

151 mg/l, 96 hours OECD 203

Golden ide/orfe (Adult Leuciscus idus)

87 mg/l, 96 hours German std DIN 38412 Part 15

*Chronic*

Algae

NOEC

Green algae (Desmodesmus subspicatus)

6.25 mg/l, 72 hours OECD 201

## DODECYL SODIUM SULFATE (CAS 151-21-3)

**Aquatic***Acute*

Crustacea

EC50

Water flea (Daphnia magna)

5.4 mg/l, 48 hours Static test

Fish

EC50

Rainbow trout (Adult Oncorhynchus mykiss)

4.6 mg/l, 96 hours Flow-through test

*Chronic*

Algae

NOEC

Green algae (Desmodesmus subspicatus)

30 mg/l, 72 hours

Crustacea

NOEC

Ceriodaphnia dubia

0.88 mg/l, 7 days Flow-through Test

Fish

NOEC

Fathead minnow (Pimephales promelas)

3.8 mg/l, 28 days Flow-through test

## HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)

**Aquatic***Acute*

Fish

EC50

Fish

&gt; 100 mg/l, 96 hours

Components		Species	Test results
L-ASCORBIC ACID (CAS 50-81-7)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	1020 mg/l, 96 hours
PARACETAMOL (CAS 103-90-2)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.86 mg/l, 48 hours Measured
	NOEC	Daphnia	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss)	100 mg/l, 96 hours
Polyvinylpyrrolidone (CAS 9003-39-8)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
POTASSIUM SORBATE (CAS 24634-61-5)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	750 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 500 mg/l, 96 hours Static test
		Zebra fish (Adult Brachydanio rerio)	1250 mg/l, 48 hours
			> 1000 mg/l, 96 hours
<i>Chronic</i>			
Crustacea	EC50	Water flea (Daphnia magna)	901 mg/l, 24 hours
Other	EC50	Bacteria	5000 mg/l, 21 hours
Propylene glycol (CAS 57-55-6)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days

Components		Species	Test results
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
Stearic acid (CAS 57-11-4)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 32 mg/l, 47 hours EU Method C.2
Fish	LC0	Carp (Cyprinus carpio)	1000 mg/l, 48 hours OECD 203
Talc (CAS 14807-96-6)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test

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

## Persistence and degradability

### Photolysis

#### Half-life (Photolysis-aqueous)

Propylene glycol 1.3 - 2.3 years Estimated

#### Half-life (Photolysis-atmospheric)

CAFFEINE 2.5 Hours Estimated

Propylene glycol 32 Hours Estimated

Stearic acid 17 Hours Estimated

#### UV/visible spectrum wavelength

CAFFEINE 227 nm

Stearic acid 210 nm

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

L-ASCORBIC ACID 100 %, 15 days Zahn-Wellens

PARACETAMOL 99 %, 5 days Modified Zahn-Wellens, Activated sludge

PHENYLEPHRINE HYDROCHLORIDE 81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

POTASSIUM SORBATE 95 %, 6 days Zahn-Wellens

Polyvinylpyrrolidone 0 %, 28 days Modified MITI test, Activated sludge

Propylene glycol 62 %, 5 days BOD5, Activated sludge

79 %, 20 Days BOD20, Activated sludge

Stearic acid 77 %, 28 days BOD

#### Percent degradation (Aerobic biodegradation-ready)

DODECYL SODIUM SULFATE 95 % OECD 301 B

Stearic acid 95 %, 22 days Sturm test

#### Percent degradation (Aerobic biodegradation-soil)

Stearic acid 50 %, 13 days

#### Percent degradation (Anaerobic biodegradation)

Propylene glycol 100 %, 9 days

## Bioaccumulative potential



**Partition coefficient  
n-octanol / water (log Kow)**

CAFFEINE	-0.07
	-0.0907
DODECYL SODIUM SULFATE	1.6
HYDROXYPROPYL METHYL CELLULOSE	-5
L-ASCORBIC ACID	-2.15
PARACETAMOL	0.36
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).
Propylene glycol	-0.92
	-1.35
Stearic acid	8.23
	8.42

**Bioconcentration factor  
(BCF)**

CAFFEINE	0.52 - 2.25 Estimated
HYDROXYPROPYL METHYL CELLULOSE	3.2 Estimated
Propylene glycol	< 1 Estimated
Stearic acid	> 9999 Estimated

**Mobility in soil** Not available.

**Adsorption**

**Soil/sediment sorption - log Koc**

CAFFEINE	1.25 - 1.34 Estimated
Stearic acid	5.86 Estimated

**Volatility**

**Henry's law**

CAFFEINE	0 atm m <sup>3</sup> /mol Estimated
HYDROXYPROPYL METHYL CELLULOSE	0 atm m <sup>3</sup> /mol Estimated
PARACETAMOL	0 atm m <sup>3</sup> /mol Estimated
Propylene glycol	0 atm m <sup>3</sup> /mol Estimated
Stearic acid	0.000051 Estimated

**Other adverse effects** Not available.

### 13. Disposal considerations

<b>Disposal methods</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Residual waste</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

**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** Not applicable.

### 15. Regulatory information

**Safety, health and environmental regulations**

**National regulations** This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

**Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix B**

POLYVINYLPIRROLIDONE (CAS 9003-39-8)  
POTASSIUM SORBATE (CAS 24634-61-5)  
PROPYLENE GLYCOL (CAS 57-55-6)  
STEARIC ACID (CAS 57-11-4)

Low toxicity. Veterinary  
Low toxicity. Agricultural: Fungicide  
Low toxicity. General: Any use  
Low toxicity. General: Any use

**Australia Medicines & Poisons Appendix C**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix D**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix E**

DODECYL SODIUM SULFATE (CAS 151-21-3)

for external use for the treatment of cats and dogs in preparations  
If in eyes wash out immediately with water.  
in other [unspecified] preparations If in eyes wash out immediately  
with water., If skin or hair contact occurs, remove contaminated  
clothing and flush skin and hair with running water.

**Australia Medicines & Poisons Appendix F**

PARACETAMOL (CAS 103-90-2)

applies to all preparations in any concentration Use Warning  
Statement 97 and/or Warning Statement 98., Adults: Keep to the  
recommended dose. Don't take this medicine for longer than a few  
days at a time unless advised to by a doctor., Children and  
adolescents: Keep to the recommended dose. Do not give this  
medicine for longer than 48 hours at a time unless advised to by a  
doctor., If an overdose is taken or suspected, ring the Poisons  
Information Centre (Australia 131 - 126; New Zealand 0800 - 764 -  
766) or go to a hospital straight away even if you feel well

**Australia Medicines & Poisons Appendix G**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix H**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix I**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix J**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix K**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 2**

PARACETAMOL (CAS 103-90-2)

for therapeutic use Exception may apply, see the regulation for  
relevance.

**Australia Medicines & Poisons Schedule 3**

PARACETAMOL (CAS 103-90-2)

> 10

**Australia Medicines & Poisons Schedule 4**

HYDROXYPROPYL METHYL CELLULOSE (CAS  
9004-65-3)  
PARACETAMOL (CAS 103-90-2)

in preparations for injection

applies to all preparations in any concentration Exception may  
apply, see the regulation for relevance.

**Australia Medicines & Poisons Schedule 5**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 6**

DODECYL SODIUM SULFATE (CAS 151-21-3)

applies to all preparations in any concentration Exception may  
apply, see the regulation for relevance.

**Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 8**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 9**

Poisons schedule number not allocated.

**High Volume Industrial Chemicals (HVIC)**

PROPYLENE GLYCOL (CAS 57-55-6)

1000 - 9999 TONNES See the regulation for additional  
information.

TALC (CAS 14807-96-6)

100000 - 999999 TONNES See the regulation for additional  
information.

**Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)**

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Not listed.

**Prohibited Carcinogenic Substances**

Not regulated.

**Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)**

Not listed.

**Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)**

Not listed.

**Restricted Carcinogenic Substances**

Not regulated.

**International regulations****Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**Kyoto protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information****Issue date** 25-August-2014**Revision date** 25-August-2014**References** GSK Hazard Determination**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.**Revision Information** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients