

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	NIGHT NURSE CAPSULES
Registration number	-
Synonyms	PARACETAMOL, PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE, FORMULATED PRODUCT
Issue date	29-August-2014
Version number	14
Revision date	29-August-2014

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

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

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

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

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

2.2. Label elements

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

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

Supplemental label information None.

2.3. Other hazards Caution - Pharmaceutical agent.
See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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PARACETAMOL	< 90	103-90-2 203-157-5	-	-	
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Classification: **DSD:** Xn;R22, R52/53
CLP: Acute Tox. 4;H302, Aquatic Chronic 3;H412

LACTOSE	< 12	63-42-3 200-559-2	-	-	
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Classification: **DSD:** -
CLP: -

PROMETHAZINE HYDROCHLORIDE	< 2	58-33-3 200-375-2	-	-	
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Classification: **DSD:** Xn;R22, N;R51/53
CLP: Acute Tox. 4;H302, Aquatic Chronic 2;H411

DEXTROMETHORPHAN HYDROBROMIDE	< 1,5	125-69-9 204-750-1	-	-	
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Classification: **DSD:** Xn;R22, N;R51/53
CLP: Acute Tox. 4;H302, Aquatic Chronic 2;H411

Silicon dioxide	< 0,25	7631-86-9 231-545-4	-	-	
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Classification: **DSD:** -
CLP: -

Other components below reportable levels < 1

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

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

SECTION 4: First aid measures

General information Take off all contaminated clothing immediately. 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. Wash contaminated clothing before reuse.

4.1. Description of first aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Take off immediately all contaminated clothing. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.

Ingestion 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.

4.2. Most important symptoms and effects, both acute and delayed Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards	No unusual fire or explosion hazards noted.
5.1. Extinguishing media	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	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. 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.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	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.
6.3. Methods and material for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	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.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components

	Type	Value
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)	8 HR TWA	10 mcg/m3
	OHC	4
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)	8 HR TWA	10 mcg/m3
	OHC	4
Silicon dioxide (CAS 7631-86-9)	OHC	1

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.
8.2. Exposure controls	
Appropriate engineering controls	Explosion-proof general and local exhaust ventilation. 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. 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, such as personal protective equipment	
General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin protection	
- Hand protection	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. Glove selection must take into account any solvents and other hazards present. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. When using do not smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has been developed for this material.
Environmental exposure controls	
Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Capsule.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Alkali metals.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion	Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed. Health injuries are not known or expected under normal use.

Components	Species	Test results
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)		
Acute		
Oral		
LD50	Rat	350 mg/kg
LACTOSE (CAS 63-42-3)		
Acute		
Oral		
LD50	Rat	> 10 g/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous

Components	Species	Test results
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
TD	Mouse	6100 ppm, 13 weeks dietary, continuous 1,25 %, 41 weeks dietary, continuous
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	326 mg/kg
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Irritation Corrosion - Skin: P.I.I. value		
PARACETAMOL		OECD 404, Literature data Result: Slight irritant Species: Rabbit
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use.	
Eye		
PARACETAMOL		OECD 405 Result: Slight irritant Species: Rabbit
Eye / Initial pain reaction score		
PARACETAMOL		Literature data
Respiratory sensitisation	Health injuries are not known or expected under normal use.	
Skin sensitisation	Health injuries are not known or expected under normal use.	
Sensitisation		
DEXTROMETHORPHAN HYDROBROMIDE		SAR, DEREK, Lhasa, UK Result: positive
Germ cell mutagenicity	Health injuries are not known or expected under normal use.	
Mutagenicity		
DEXTROMETHORPHAN HYDROBROMIDE		Ames Result: negative Notes: Global Safety Datasheet.
PARACETAMOL		Ames, Literature data Result: negative Chromosomal Aberration Assay In Vitro, Literature data Result: positive HPRT gene mutation in human lymphocytes, Literature data Result: negative
DEXTROMETHORPHAN HYDROBROMIDE		In vitro cytogenetics assay Result: negative Notes: Aardema A et al, Reg Tox Pharm.
PARACETAMOL		In vivo Micronucleus, Literature data Result: negative Species: Mouse
Carcinogenicity	Health injuries are not known or expected under normal use.	
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

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)

3 Not classifiable as to carcinogenicity to humans.

SILICON DIOXIDE (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

Health injuries are not known or expected under normal use. 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.

Reproductivity

PARACETAMOL

250 mg/kg/day Embryofetal Development, Literature data
Result: Foetal NOAEL

Species: Rat

387 mg/kg/day Embryofetal Development, Literature data

Result: negative

Species: Mouse

750 mg/kg/day Embryofetal Development, Literature data

Result: decrease in foetal weight, minor skeletal abnormalities.

Species: Rat

<= 1400 mg/kg/day Pre- and Post-natal development, Literature data

Result: reduced weight gain during nursing.

Species: Rat

DEXTROMETHORPHAN HYDROBROMIDE

<= 50 mg/kg/day Fertility

Result: No adverse effects on fertility, or development.

Species: Rabbit

Notes: Global Safety Datasheet.

<= 50 mg/kg/day Fertility

Result: No adverse effects on fertility, or development.

Species: Rat

Notes: Global Safety Datasheet.

PARACETAMOL

Epidemiology, Literature data

Result: No clear association with therapeutic use.

Species: Human

Specific target organ toxicity - single exposure

May cause damage to organs by ingestion.

DEXTROMETHORPHAN HYDROBROMIDE

Organ: Central nervous system.

PARACETAMOL

Species: Human

Organ: Liver

Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure by ingestion.

Aspiration hazard

Not likely, due to the form of the product.

Mixture versus substance information

No information available.

Other information

Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity

Contains a substance which causes risk of hazardous effects to the environment.

Components

Species

Test results

DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)

Aquatic

Acute

Algae

EC50

Algae

2,28 mg/l, 72 hours

NOEC

Algae

0,35 mg/l, 72 hours

Crustacea

EC50

Water flea (Daphnia magna)

13,78 mg/l, 48 hours

NOEC

Water flea (Daphnia magna)

< 5,51 mg/l, 48 hours

Fish

EC50

Rainbow trout (Adult Oncorhynchus mykiss)

4,66 mg/l, 96 hours

Chronic

Other

LC50

Bacteria

> 100 mg/l, 3 hours

PARACETAMOL (CAS 103-90-2)

Aquatic

Acute

Algae

EC50

Green algae (Scenedesmus subspicatus)

134 mg/l, 72 hours

Components		Species	Test results
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

PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)

Aquatic

Acute

Crustacea	EC50	Water flea (Daphnia magna)	1,5 mg/l, 48 hours
Fish	EC50	Fish	2 mg/l, 96 hours

Silicon dioxide (CAS 7631-86-9)

Aquatic

Acute

Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

12.2. Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
	0 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days
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12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

PARACETAMOL	0,36
PROMETHAZINE HYDROCHLORIDE	-0,72

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

LACTOSE	1 Calculated
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Mobility in general

Volatility

Henry's law

LACTOSE	< 0 atm m ³ /mol Calculated
PARACETAMOL	0 atm m ³ /mol Estimated

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste

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).

Contaminated packaging

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.

EU waste code

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. Dispose in accordance with all applicable regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R22 Harmful if swallowed. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H302 Harmful if swallowed. H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: TOXICOLOGICAL INFORMATION: Regulatory Information: Risk Phrases - Class. GHS: Classification
Training information	Follow training instructions when handling this material.
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.