

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 30-Oct-2023

Revision Number 1

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

### 1.1. Product identifier

**Product Code(s)** CAT 800  
**Product Name** Isosorbide mononitrate Assay Standard  
**Form** Not applicable

*NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II*

**EC No (EU Index No)** 240-197-2  
**CAS No.** 16051-77-7  
**Chemical name** Isosorbide mononitrate  
**Pure substance/mixture** Substance  
**Formula** C<sub>6</sub> H<sub>9</sub> N O<sub>6</sub>  
**Molecular weight** 191.14

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

**Recommended use** Laboratory use  
**Uses advised against** No information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

British Pharmacopoeia Commission  
MHRA  
10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom

Tel : +44 (0)20 3080 6561  
eMail: bpcrs@mhra.gov.uk

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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

### 1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to  
Regulation (EC) No. 1272/2008 [CLP]

Flammable solids	Category 2 - (H228)
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### 2.2. Label elements



**Signal word**  
Warning

**Hazard statements**  
H228 - Flammable solid

#### Precautionary Statements - EU (§28, 1272/2008)

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking  
P240 - Ground and bond container and receiving equipment  
P241 - Use explosion-proof electrical/ ventilating/ lighting/ equipment  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P370 + P378 - In case of fire: Use dry chemical, CO2, water spray or alcohol-resistant foam to extinguish

### 2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Isosorbide mononitrate	-	-

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No.	Specific concentration	M-Factor	M-Factor (long-term)
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				1272/2008 [CLP]	limit (SCL)		
Isosorbide mononitrate 16051-77-7	90 - 100%	-	240-197-2	Flam. Sol. 2 (H228)			

**Full text of H- and EUH-phrases: see section 16**

### Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Isosorbide mononitrate 16051-77-7	2010	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Ingestion</b>	Rinse mouth.
<b>Self-protection of the first aider</b>	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8).

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

Symptoms No information available.

### 4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray. Alcohol resistant foam.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.

Other information Ventilate the area.

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**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapour suppressing foam may be used to reduce vapours. Keep out of drains, sewers, ditches and waterways.

**Methods for cleaning up** Take precautionary measures against static discharges. Pick up and transfer to properly labelled containers.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Advice on safe handling** Use personal protection equipment. Avoid contact with skin and eyes. Avoid breathing vapours or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Please refer to the manufacturer's certificate for specific storage and transport temperature

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conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labelled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations.

### 7.3. Specific end use(s)

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### **Exposure Limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### **Derived No Effect Level (DNEL)**

No information available.

#### **Predicted No Effect Concentration (PNEC)**

No information available.

### 8.2. Exposure controls

#### **Personal protective equipment**

##### **Eye/face protection**

Avoid contact with eyes. Wear safety glasses with side shields (or goggles). Tight sealing safety goggles.

##### **Hand protection**

Wear suitable gloves. Impervious gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves.

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<b>Skin and body protection</b>	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.
<b>Environmental exposure controls</b>	Do not allow into any sewer, on the ground or into any body of water.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Solid
<b>Colour</b>	white
<b>Odour</b>	Odourless.
<b>Odour threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	86 - 88 °C	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>	No data available	No information available
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known



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Water solubility	Soluble in water	None known
Solubility(ies)	Chloroform, Methanol, slightly soluble	
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

### 9.2. Other information

Molecular weight	191.14
Molecular formula	C <sub>6</sub> H <sub>9</sub> N O <sub>6</sub>

9.2.1. Information with regards to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge Yes.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

### 10.4. Conditions to avoid

Conditions to avoid Heat, flames and sparks.

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### 10.5. Incompatible materials

**Incompatible materials** None known based on information supplied.

**Hazardous decomposition products** None known based on information supplied.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Information on likely routes of exposure

##### Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

#### Numerical measures of toxicity

##### Acute toxicity

##### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Isosorbide mononitrate	= 2010 mg/kg ( Rat )		

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

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**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitisation** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

**Reproductive toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

#### 11.2.2. Other information

**Other adverse effects** No information available.

## SECTION 12: Ecological information

### 12.1. Toxicity

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**Ecotoxicity** The environmental impact of this product has not been fully investigated.

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Chemical name	PBT and vPvB assessment
Isosorbide mononitrate	The substance is not PBT / vPvB

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Waste from residues/unused products** Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

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### SECTION 14: Transport information

#### IATA

14.1 UN number or ID number	UN3251
14.2 UN proper shipping name	Isosorbide-5-mononitrate
14.3 Transport hazard class(es)	4.1
14.4 Packing group	III
Description	UN3251, Isosorbide-5-mononitrate, 4.1, III
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	A110
ERG Code	3L
Note:	Forbidden

#### IMDG

14.1 UN number or ID number	UN3251
14.2 UN proper shipping name	Isosorbide-5-mononitrate
14.3 Transport hazard class(es)	4.1
14.4 Packing group	III
Description	UN3251, Isosorbide-5-mononitrate, 4.1, III
14.5 Marine pollutant	NP
14.6 Special precautions for user	
Special Provisions	226
EmS-No.	F-F, S-G No information available
14.7 Maritime transport in bulk according to IMO instruments	No information available

#### RID

14.1 UN number or ID number	UN3251
14.2 UN proper shipping name	Isosorbide-5-mononitrate
14.3 Transport hazard class(es)	4.1
14.4 Packing group	III
Description	UN3251, Isosorbide-5-mononitrate, 4.1, III
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	226, 638
Classification code	SR1

#### ADR

14.1 UN number or ID number	UN3251
14.2 UN proper shipping name	Isosorbide-5-mononitrate

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14.3 Transport hazard class(es)	4.1
14.4 Packing group	III
Description	UN3251, Isosorbide-5-mononitrate, 4.1, III, (D)
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	226, 638
Classification code	SR1
Tunnel restriction code	(D)

## SECTION 15: Regulatory information

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

Water hazard class (WGK) slightly hazardous to water (WGK 1)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the

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management of packaging and packaging waste, Journal of Laws 2013, item 888).  
Government statement of September 24, 2002 - European Agreement on the  
International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194,  
item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

#### European Union

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

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

#### Persistent Organic Pollutants

Not applicable

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

#### International Inventories

##### TSCA

Complies under research and development exemption or is regulated by a different government agency.

##### DSL/NDSL

Contact supplier for inventory compliance status

##### EINECS/ELINCS

Contact supplier for inventory compliance status

##### ENCS

Contact supplier for inventory compliance status

##### IECSC

Contact supplier for inventory compliance status

##### KECL

Contact supplier for inventory compliance status

##### PICCS

Contact supplier for inventory compliance status

##### AIIC

Contact supplier for inventory compliance status

#### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

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**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

#### Chemical Safety Report

A Chemical Safety Assessment is not required for this substance

## SECTION 16: Other information

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H228 - Flammable solid

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average)  
Ceiling Maximum limit value

STEL  
\*

STEL (Short Term Exposure Limit)  
Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method



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STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method
Flammable solids	On basis of test data

### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AELG(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme  
Organisation for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

### Disclaimer

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End of Safety Data Sheet