

Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

Quality standards

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
	nber is given for this substance because it is under the threshold in REACH Article istration 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	C6 H9 N O6
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 sa	afety 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 - REAC	H (1907/2006) - Article	e 59(1) EU - REACH (1907/2006) - Endocrine
	- Candidate	e List of Substances of	f Very Disruptor Assessment List of
	High Conce	ern (SVHC) for Authori	isation Substances
Isosorbide mononitra	te	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
		number	Index No)	to Regulation (EC) No.	concentration		(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

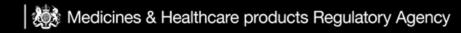
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/l	Inhalation LC50 - 4 hour - gas - ppm
Isosorbide mononitrate 16051-77-7	2010	No data available	<u> </u>	No data available	No data available

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	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.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Ingestion	Rinse mouth.
Self-protection of the first aider	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 s	ymptoms 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

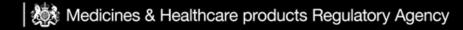
5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical. Carbon dioxide (CO2). 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 th	e 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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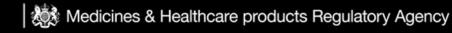
For amount of the second	Lice neuronal protection recommon ded in Contine 0
For emergency responders	Use personal protection recommended in Section 8.
6.2. Environmental precautions	
Environmental precautions	Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.
6.3. Methods and material for conta	inment 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, in	cluding 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) Predicted No Effect Concentration (PNEC)	No information available. 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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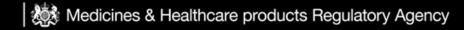
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Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
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.
Environmental exposure controls	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		
Physical state	Solid	
Appearance	Solid	
Colour	white	
Odour	Odourless.	
Odour threshold	No information available	
Property	Values	Remarks • Method
_	<u>values</u> 86 - 88 °C	None known
Melting point / freezing point		
Initial boiling point and boiling rang		None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
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Water solubility	Soluble in water	None known
Solubility(ies) Partition coefficient	Chloroform, Methanol, slightly soluble No data available	None known
	No data available	None known
Vapour pressure		
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	

C6 H9 N O6

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

Molecular formula

Reactivity

No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

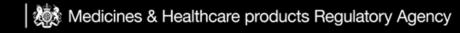
Explosion data Sensitivity to mechanical impact None. Sensitivity to static discharge Yes.

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

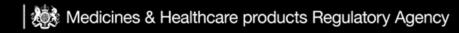
Numerical measures of toxicity

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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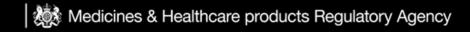
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Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	No information available.	
Respiratory or skin sensitisation	No information available.	
Germ cell mutagenicity	No information 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 prope	erties	
Endocrine disrupting properties	No information available.	
11.2.2. Other information		
Other adverse effects	No information available.	
SECTION 12: Ecological in	formation	

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		to be persistent, bioaccumulating nor toxic (PBT). This every 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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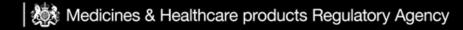
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SECTION 14: Transport information

IATA

 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions ERG Code Note: 	UN3251 Isosorbide-5-mononitrate 4.1 III UN3251, Isosorbide-5-mononitrate, 4.1, III Not applicable A110 3L Forbidden
 IMDG 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Marine pollutant 14.6 Special precautions for user Special Provisions EmS-No. 14.7 Maritime transport in bulk according to IMO instruments 	UN3251 Isosorbide-5-mononitrate 4.1 III UN3251, Isosorbide-5-mononitrate, 4.1, III NP 226 F-F, S-G No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing groupDescription14.5Environmental hazards14.6Special precautions for userSpecial ProvisionsClassification code	UN3251 Isosorbide-5-mononitrate 4.1 III UN3251, Isosorbide-5-mononitrate, 4.1, III Not applicable 226, 638 SR1
ADR 14.1 UN number or ID number 14.2 UN proper shipping name	UN3251 Isosorbide-5-mononitrate





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14.3 Transport hazard class(es) 14.4 Packing group	4.1 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

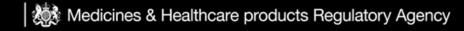
Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

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

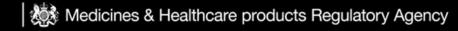
Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	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) (AEGL(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