

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 23-Apr-2024

Revision Number 1

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

1.1. Product identifier	
Product Code(s)	CAT 853

Product Name Amikacin sulfate Assay Standard

Not applicable Form

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)	254-648-6		
CAS No.	39831-55-5		
Pure substance/mixture	Substance		
Formula	C ₂₂ H ₄₇ N ₅ O ₂₁ S ₂		
Molecular weight	781.76		
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			
<u>Supplier</u>			
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

For further information, please contact





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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		

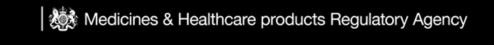
SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

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

Acute toxicity - Inhalation (Dusts/Mists)	Category 4 - (H332)
Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitisation	Category 1 - (H317)
Specific target organ toxicity — repeated exposure	Category 1 - (H372)





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2.2. Label elements



Signal wor Danger

Hazard statements

H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H332 - Harmful if inhaled
H372 - Causes damage to organs through prolonged or repeated exposure

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

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P280 - Wear protective gloves and eye/face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor

P362 + P364 - Take off contaminated clothing and wash it before reuse

2.3. Other hazards

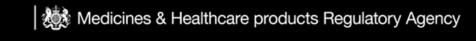
No information available.

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)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Amikacin Sulfate	-	-

SECTION 3: Composition/information on ingredients





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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)
				1272/2008 [CLP]	limit (SCL)		
Amikacin Sulfate	100	-	254-648-6	Acute Tox. 4 (H332)			
39831-55-5				Eye Dam. 1 (H318)			
				Skin Sens. 1 (H317)			
				STOT RE 1 (H372)			

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

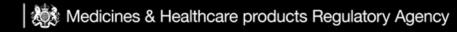
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Amikacin Sulfate 39831-55-5	4000	No data available		No data available	No data available

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

General advice	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air. Get medical attention immediately if symptoms occur. If breathing has stopped, give artificial respiration. Get medical attention immediately. If symptoms persist, call a doctor.
Eye contact	Get immediate medical attention. Rinse immediately with plenty of water, also under the





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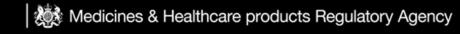
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	eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.	
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.	
Ingestion	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Get medical attention.	
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid breathing dust/fume/gas/mist/vapours/spray. Use personal protective equipment as required. See section 8 for more information.	
4.2. Most important symptoms and	effects, both acute and delayed	
Symptoms	Burning sensation. Itching. Rashes. Hives. Coughing and/ or wheezing. Difficulty in breathing.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to doctors	May cause sensitisation in susceptible persons. Treat symptomatically.	
SECTION 5: Firefighting m	003511705	
5.1. Extinguishing media	leasures	
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
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		
	ne substance or mixture	
Specific hazards arising from the chemical	Product is or contains a sensitiser. May cause sensitisation by skin contact.	





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SECTION 6: Accidental release measures

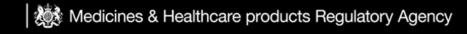
6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Ensure adequate ventilation. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid generation of dust. Do not breathe dust.	
Other information	Refer to protective measures listed in Sections 7 and 8.	
For emergency responders	Use personal protection recommended in Section 8.	
6.2. Environmental precautions		
Environmental precautions	Prevent further leakage or spillage if safe to do so.	
6.3. Methods and material for conta	inment and cleaning up	
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.	
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	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Take off contaminated clothing and wash it before reuse. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid generation of dust.
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





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protection. Avoid breathing dust/fume/gas/mist/vapours/spray.

7.2. Conditions for safe storage, including any incompatibilities

Storage ConditionsPlease refer to the manufacturer's certificate for specific storage and transport temperature
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. Store locked up.
Keep out of the reach of children.

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.

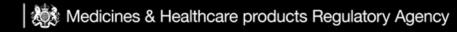
Biological occupational exposure limits

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 ConcentrationNo information available.(PNEC)No

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. The protective gloves to be used must comply with the specifications





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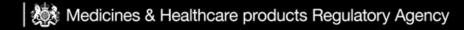
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	of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If 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. Avoid breathing dust/fume/gas/mist/vapours/spray.
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 to off-white	
Odour	No information available.	
Odour threshold	No information available	
Property_	Values	Remarks • Method
Melting point / freezing point	>210	None known
Initial boiling point and boiling rang	eNo data available	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
Water solubility	No data available	None known
•		





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None known None known None known None known

None known

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Solubility(ies) Partition coefficient	No data available No data available
Vapour pressure	No data available
Relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Relative vapour density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
9.2. Other information	781.76
Molecular weight Molecular formula	
	C 22H 47N 5O 21S 2

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.

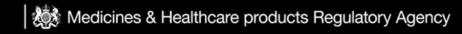
Explosion data Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Excessive heat.





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10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

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. Harmful by inhalation. (based on components).
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye damage. May cause irreversible damage to eyes.
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation. May cause sensitisation by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Symptoms related to the physical,	chemical and toxicological characteristics
Symptoms	Redness. Burning. May cause blindness. Itching. Rashes. Hives. Coughing and/ or wheezing.
Numerical measures of toxicity	

Acute toxicity

Component Information





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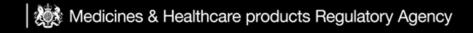
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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Amikacin Sulfate	> 4 g/kg (Rat)		

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

Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes burns. Causes serious eye damage.
Respiratory or skin sensitisation	May cause an allergic skin reaction.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	No information available.
11.2. Information on other hazards	<u>8</u>
11.2.1. Endocrine disrupting prope	erties
Endocrine disrupting properties	No information available.

11.2.2. Other information





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Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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 No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

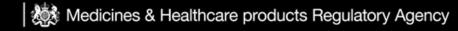
12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused	Dispose of in accordance with local regulations. Dispose of waste in accordance with
products	environmental legislation.





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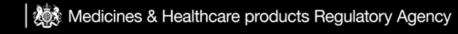
Contaminated packaging

Do not reuse empty containers.

SECTION 14: Transport information

ΙΑΤΑ

IATA	
14.1 UN number or ID nu	Imber Not regulated
14.2 UN proper shipping	name Not regulated
14.3 Transport hazard cl	•
14.4 Packing group	Not regulated
14.5 Environmental haza	0
14.6 Special precautions	
Special Provisions	None
opecial i revisions	
IMDG	
14.1 UN number or ID nu	mber Not regulated
14.2 UN proper shipping 14.3 Transport hazard cl	
	Not regulated
14.4 Packing group 14.5 Marine pollutant	
	Not applicable
14.6 Special precautions	
Special Provisions	None No information available
14.7 Maritime transport i	
according to IMO instrum	ents
<u>RID</u>	Net an available d
14.1 UN number or ID nu	U
14.2 UN proper shipping	
14.3 Transport hazard cl	
14.4 Packing group	Not regulated
14.5 Environmental haza	
14.6 Special precautions	
Special Provisions	None
ADR	
14.1 UN number or ID nu	
14.2 UN proper shipping	
14.3 Transport hazard cl	
14.4 Packing group	Not regulated
14.5 Environmental haza	
14.6 Special precautions	
Special Provisions	None





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SECTION 15: Regulatory information

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

National regulations

Germany

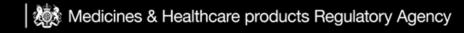
Water hazard class (WGK)

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 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





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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

DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS AIIC LGC has not confirmed that the chemical substances in this product are on the TSCA Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the requirements that apply to its use of this product. Contact supplier for inventory compliance status Contact supplier for inventory compliance status

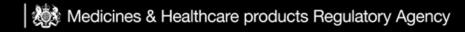
Legend:

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

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

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

Contact supplier for inventory compliance status





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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

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H332 - Harmful if inhaled

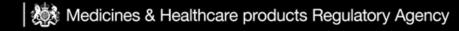
H372 - Causes damage to organs through prolonged or repeated exposure

Legend

SVHC: Substances of Very High Concern for Authorisation:

LegendSection 8: Exposure controls/personal protectionTWATWA (time-weighted average)STELCeilingMaximum limit valueSk*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





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Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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

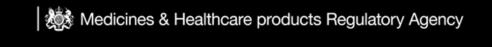
Organisation for Economic Co-operation and Development Screening Information Data Set

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