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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 28-Nov-2023

Revision Number 1

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

1.1. Product identifier	
Product Code(s)	CAT 775
Product Name	Salicylic acid
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)	200-712-3
CAS No.	69-72-7
Pure substance/mixture	Substance
Formula	C7H6O3
Molecular weight	138.12

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

Uses advised against No information available

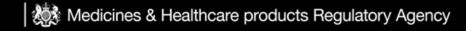
1.3. Details of the supplier of the safety data sheet

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

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	

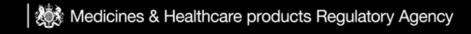
SECTION 2: Hazards identification

2.1. Classification of the substance or mixture Classification according to

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

Acute toxicity - Oral	Category 4 - (H302)
Serious eye damage/eye irritation	Category 1 - (H318)
Reproductive toxicity	Category 2 - (H361)

2.2. Label elements





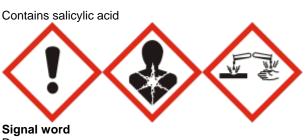
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Danger

Hazard statements

H302 - Harmful if swallowed H318 - Causes serious eye damage H361d - Suspected of damaging the unborn child

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

P201 - Obtain special instructions before use
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/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
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

No information available.

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

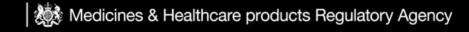
Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

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
salicylic acid	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name Weight-% REACH registration EC No (EU Classification according Specific M-Factor M-Factor





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		number	Index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)	(long-term)
salicylic acid	90 -	-	200-712-3	Acute Tox. 4 (H302)		
69-72-7	100%		(607-732-00	Eye Dam. 1 (H318)		
			-5)	Repr. 2 (H361d)		

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

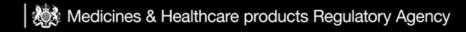
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
salicylic acid 69-72-7	891	2000	No data available	No data available	No data available

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	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.	
Inhalation	Remove to fresh air. Get medical attention immediately if symptoms occur.	
Eye contact	Get immediate medical attention. 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 for at least 15 minutes. Get medical attention if irritation develops and persists.	
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.	
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).	
4.2. Most important symptoms and effects, both acute and delayed		





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Symptoms Burning sensation.

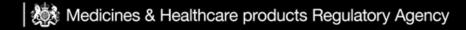
4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable Extinguishing Media	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		
Specific hazards arising from the chemical	No information available.	
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	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
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 containment and cleaning up	
Methods for containment	Prevent further leakage or spillage if safe to do so.





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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. Remove contaminated clothing and shoes.	
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. 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 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 out of the reach of children. Store locked up.	

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

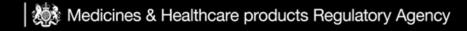
8.1. Control parameters

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





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regulatory bodies

Derived No Effect Level (DNEL) No information available. Predicted No Effect Concentration (PNEC)

8.2. Exposure controls

Personal protective equipment

Eye/face protectionAvoid contact with eyes. Wear safety glasses with side shields (or goggles). Tight sealing
safety goggles.Hand protectionThe protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves. Wear suitable 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. Wash hands before breaks and immediately after handling the product.

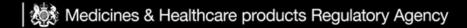
Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic ph	ysical and chemical properties
Physical state	Solid
Appearance	Crystalline powder
Colour	white
Odour	Odourless.
Odour threshold	No information available

Property	Valu	es
Melting point / freezing point	159	°C
Initial boiling point and boiling range	e 211	°C

Remarks • Method None known None known





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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	157 °C	None known
Autoignition temperature	540 °C	None known
Decomposition temperature		None known
pH	No data available	None known
I.	2.4	No information available
pH (as aqueous solution) Kinematic viscosity	No data available	None known
-	No data available	None known
Dynamic viscosity		
Water solubility	No data available	None known
Solubility(ies)	Alcohol, Benzene, Toluene, Ether	New a los accor
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	1.44	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	138.12	
Molecular formula	C7H6O3	

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

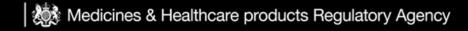
No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data





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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 None known based on information supplied.

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

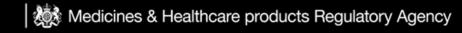
Product Information

Inhalation	Specific test data for the substance or mixture is not available.	
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.	
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components).	
Symptoms related to the physical, chemical and toxicological characteristics		

Symptoms Redness. Burning. May cause blindness.

Numerical measures of toxicity

Acute toxicity





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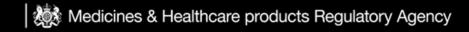
Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
salicylic acid	= 891 mg/kg (Rat)	> 2 g/kg (Rat)	> 900 mg/m³ (Rat)1 h	
Delayed and immediate effects	as well as chronic effects fror	n short and long-term exposur	e	
Skin corrosion/irritation	May cause skin irritation.			
Serious eye damage/eye irritat	on Classification based on da damage.	ta available for ingredients. Caus	ses burns. Causes serious eye	
Respiratory or skin sensitisation	on No information available.			
Germ cell mutagenicity	No information available.			
Carcinogenicity	No information available.			
Reproductive toxicity	for ingredients. Suspected	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.		
The table below indicates ingredients above the cut-off threshold considered as relevant which are listed as reproductive toxins.				
Chemic	al name	Europea	an Union	
salicylic acid Repr. 2		or. 2		

- **STOT single exposure** No information available.
- **STOT repeated exposure** No information available.
- Aspiration hazard

No information available.

11.2. Information on other hazards





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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

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
salicylic acid	-	-	-	EC50: =870mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
salicylic acid	2.25

12.4. Mobility in soil

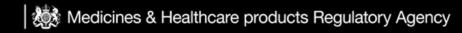
Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
salicylic acid	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties





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Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

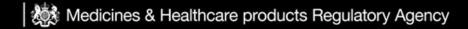
13.1. Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

SECTION 14: Transport information

<u>IATA</u>

14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards	Not regulated Not regulated Not regulated Not regulated Not applicable
14.6 Special precautions for user Special Provisions	None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group	Not regulated Not regulated Not regulated Not regulated





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14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None
ADR	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

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)

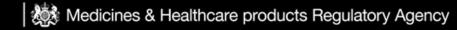
slightly hazardous to water (WGK 1)

Netherlands

Chemical name	Netherlands - List of	Netherlands - List of	Netherlands - List of
	Carcinogens	Carcinogens	Reproductive Toxins
salicylic acid	-	-	Development Category 2

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).





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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 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

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 contains one or more substance(s) 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

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
salicylic acid - 69-72-7	75.	

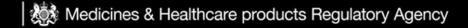
Persistent Organic Pollutants

Not applicable

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

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
salicylic acid - 69-72-7	Product-type 2: Disinfectants and algaecides not intended
	for direct application to humans or animals Product-type 3:
	Veterinary hygiene Product-type 4: Food and feed area





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International Inventories	
TSCA	Complies
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

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

H302 - Harmful if swallowed

H318 - Causes serious eye damage

H361d - Suspected of damaging the unborn child

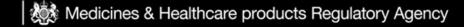
Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWĂ	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method





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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	
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	

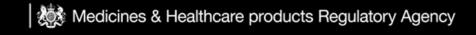
Key literature references and sources for data used to compile the SDS

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

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of





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

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