

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

Revision date 11-Jan-2022

Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 275

Product Name

Oxytetracycline Hydrochloride

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	218-161-2
CAS No	2058-46-0
Pure substance/mixture	Substance
Formula	C22H24N2O9.CIH
Molecular weight	496.9
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	fety data sheet
1.3. Details of the supplier of the sa Supplier	ifety data sheet
	ifety data sheet
Supplier British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU	ifety data sheet

For further information, please contact

E-mail address

bpcrs@mhra.gov.uk



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1.4. Emergency telephone number

Emergency Telephone

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

Emergeney Telephone SAE (EC)	4.373/2009
Emergency Telephone - §45 - (EC)	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	(+352) 8002 5500 Free telephone number with a 24/7 access in French, Dutch and English.
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

 Regulation (EC) No 1272/2008

 Skin corrosion/irritation
 Category 2 - (H315)

 Serious eye damage/eye irritation
 Category 2 - (H319)

 Reproductive toxicity
 Category 2 - (H361)

 Effects on or via lactation
 Yes - (H362)

 Specific target organ toxicity — single exposure
 Category 3 - (H335)

 Acute aquatic toxicity
 Category 1 - (H400)

 Chronic aquatic toxicity
 Category 1 - (H410)



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2.2. Label elements



Warning

Hazard statements

- H315 Causes skin irritation
- H319 Causes serious eye irritation
- H335 May cause respiratory irritation
- H361 Suspected of damaging fertility or the unborn child
- H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
- H362 May cause harm to breast-fed children
- H410 Very toxic to aquatic life with long lasting effects

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

- P260 Do not breathe dust/fume/gas/mist/vapours/spray
- P263 Avoid contact during pregnancy and while nursing
- P264 Wash face, hands and any exposed skin thoroughly after handling
- P273 Avoid release to the environment
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P391 Collect spillage

2.3. Other hazards

No information available.

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

Endocrine Disruptor Information

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
Oxytetracycline hydrochloride	-	-



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SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Oxytetracycline hydrochloride 2058-46-0	100	-	218-161-2	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repr. 2 (H361fd) Lact. (H362) STOT SE 3 (H335) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			

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

Acute Toxicity Estimate No information 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.
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.
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. Get medical attention if irritation develops and persists.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.



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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	
Symptoms	May cause redness and tearing of the eyes. 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	he substance or mixture			
Specific hazards arising from the chemical	No information available.			
E.2. Advice for firefighters				

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.
Other information	Refer to protective measures listed in Sections 7 and 8.



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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	ainment 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. Remove contaminated clothing and shoes. Take off contaminated clothing and wash it before reuse. Ensure adequate ventilation. Avoid breathing vapours or mists. In case of insufficient ventilation, wear suitable respiratory equipment.
General hygiene considerations	Wash hands before breaks and immediately after handling the product. 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.
7.2. Conditions for safe storage, inc	cluding any incompatibilities
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. 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.
7.2 Specific and use(a)	

7.3. Specific end use(s)

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



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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	No information available.
(PNEC)	

8.2. Exposure controls

Personal protective equipment

Eye/face protectionIf splashes are likely to occur, wear safety glasses with side-shields. Avoid contact with
eyes. Wear safety glasses with side shields (or goggles).

Hand protectionWear 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.

Gloves				
Duration of contact	PPE - Glove material	Glove thickness	Break through time	
	Wear protective nitrile rubber gloves	0.11 mm	480 minutes	
Skin and body protection	Long sleeved clothing. 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	Wash hands before breaks and immediately after handling the product. 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.			
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.			



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical propertie

9.1. Information on basic physical a	nd chemical properties	
Physical state	Solid	
Appearance	Powder	
Colour	yellow	
Odour	No information available.	
Odour threshold	No information available	
Property	Values	Remarks • Method
Melting point / freezing point	184 - 185 °C	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	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
Solubility(ies)	No data available	None known
Partition coefficient	-1.22	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	496.9	
Molecular formula	C22H24N2O9.CIH	

9.2.1. Information with regards to physical hazard classes Not applicable



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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 impac Sensitivity to static discharge	t None. 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	s 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 irritation. (based on components). May cause redness, itching, and pain.



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Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (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. May cause redness and tearing of the eyes.		
Numerical measures of toxicity No information available			
Acute toxicity			

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Oxytetracycline hydrochloride	=6696 mg/kg (Mouse)		

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

Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitisation	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child.



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STOT - single exposureMay cause respiratory irritation.STOT - repeated exposureNo information available.Aspiration hazardNo information available.11.2. Information on other hazardsInformation available.11.2.1. Endocrine disrupting propertiesNo information available.Endocrine disrupting propertiesNo information available.11.2.2. Other informationNo information available.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Oxytetracycline hydrochloride	EC50: 0.342 mg/L (72, Selenastrum capricornutum)	LC50: 116 mg/L (96h, Oncorhynchus mykiss)	-	EC50: 102 mg/L (48, Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

No information available.

Component Information

Chemical name

Partition coefficient



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Oxytetracycline hydrochloride	-1.22
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	12.6.	Endocrine	disru	pting	pro	perties
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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

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride)
14.3 Transport hazard class(es)	9
14.4 Packing group	
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride), 9, III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	A97, A158, A179, A197, A215
ERG Code	9L



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IMDG14.1 UN number or ID number14.2 UN proper shipping name14.3 Transport hazard class(es)14.4 Packing group Description14.5 Marine pollutant Environmental hazards14.6 Special precautions for user Special Provisions EmS-No14.7 Maritime transport in bulk according to IMO instruments	UN3077 Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride), 9, III, Marine pollutant P Yes 274, 335, 966, 967, 969 F-A, S-F No information available No information available
 <u>RID</u> 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 Classification code 	UN3077 Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride), 9, III Yes 274, 335, 375, 601 M7
 <u>ADR</u> 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 Classification code Tunnel restriction code 	UN3077 Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline hydrochloride), 9, III, (-) Yes 274, 335, 601, 375 M7 (-)

SECTION 15: Regulatory information

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



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Water hazard class (WGK) strongly hazardous to water (WGK 3) 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

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



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Persistent Organic Pollutants Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU) E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

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

International Inventories_	
TSCA	Contact supplier for inventory compliance status
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
AICS	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 has been carried out for this substance

SECTION 16: Other information

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



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H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child
H362 - May cause harm to breast-fed children
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	Ş
Ceiling	Maximum limit value	*	ç

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
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



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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 our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be heldresponsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise. End of Safety Data Sheet