

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 03-Apr-2023

Revision Number 1

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

1.1. Product identifier	
Product Code(s)	CAT 136
Product Name	Doxepin hydrochloride Assay Standard
Form	Not applicable
	tion number is given for this substance becau

cause 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)	214-966-8
CAS No	1229-29-4
Chemical name	Doxepin hydrochloride
Pure substance/mixture	Substance
Formula	C19H22CINO
Molecular weight	315.84
1.2 Polovant identified upon of the	substance or mixture and uses

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

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

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





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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone

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

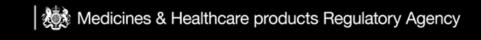
Emergency Telephone - §45 - (EC)1272/2008		
Europe	112	
Austria	No information available	
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
France		
Hungary		
Ireland		
Italy		
Lithuania		
Luxembourg		
Netherlands		
Norway		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		
Switzerland		

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 3 - (H301)
Reproductive toxicity	Category 2 - (H361)
Effects on or via lactation	Yes - (H362)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)





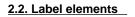
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Danger

Hazard statements

H301 - Toxic if swallowed

H361 - Suspected of damaging fertility or 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

P273 - Avoid release to the environment

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P391 - Collect spillage

2.3. Other hazards

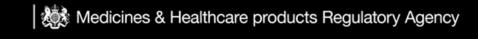
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

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
Doxepin hydrochloride	_	-

SECTION 3: Composition/information on ingredients

3.1 Substances





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Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No.		M-Factor	M-Factor (long-term)
		number		1272/2008 [CLP]	limit (SCL)		(long-tonn)
Doxepin hydrochloride 1229-29-4	90 - 100%	_	214-966-8	Acute Tox. 3 (H301) Lact. (H362) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Repr. 2 (H361)			

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

Acute Toxicity Estimate

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

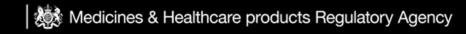
Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Doxepin hydrochloride 1229-29-4	147	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=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.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get medical attention.





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4.2. Most important symptoms and effects, both acute and delayed		
Symptoms	No information available.	

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

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

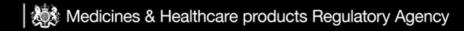
<u></u>		
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
5.2. Special hazards arising from the	e 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	Ensure adequate ventilation.	

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up





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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.	
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.	

7.3. Specific end use(s)

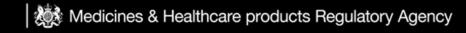
Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

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.





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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).

Hand protection

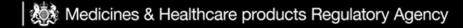
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves. Wear suitable gloves.

	Gloves		
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective butyl		
	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. 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	No information available.
Odour threshold	No information available





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Remarks • Method Property Values 187 - 189 °C Melting point / freezing point None known Initial boiling point and boiling rangeNo data available None known No data available None known Flammability 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 No data available pН None known No data available pH (as aqueous solution) No information available No data available **Kinematic viscosity** None known Dynamic viscosity No data available None known Water solubility Slightly soluble None known DMSO, Methanol, slightly soluble Solubility(ies) No data available Partition coefficient None known Vapour pressure No data available None known **Relative densitv** No data available None known **Bulk densitv** No data available Liquid Density No data available No data available None known **Relative vapour density Particle characteristics Particle Size** No information available **Particle Size Distribution** No information available 9.2. Other information Molecular weight 315.84

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

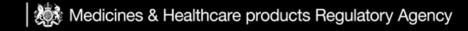
Molecular formula

Reactivity

No information available.

C19H22CINO

10.2. Chemical stability





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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 None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

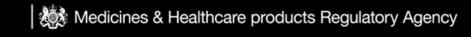
Inhalation	Specific test data for the substance or mixture is not available.	
Eye contact	Specific test data for the substance or mixture is not available.	
Skin contact	Specific test data for the substance or mixture is not available.	
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).	

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

No information available.

Numerical measures of toxicity





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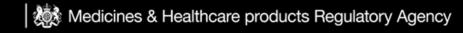
Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Doxepin hydrochloride	= 147 mg/kg (Rat)		

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

- Skin corrosion/irritation Based on available data, the classification criteria are not met. Serious eye damage/eye irritation No information available. No information available. Respiratory or skin sensitisation 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. STOT - single exposure No information available. **STOT - repeated exposure** No information available. No information available. Aspiration hazard 11.2. Information on other hazards
- 11.2.1. Endocrine disrupting properties





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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

Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Doxepin hydrochloride	EC50: 0.5-0.73 mg/L (72h, Algae)	LC50: 0.57µg/L (96h, Fish)	-	EC50: 11.1mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available	e.
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12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

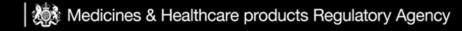
12.5. Results of PBT and vPvB assessment

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.





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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

IATA

Notes No components found suitable for Technical Name. 14.1 UN number or ID number UN2811 14.2 UN proper shipping name Toxic solid, organic, n.o.s. 14.3 Transport hazard class(es) 6.1 14.4 Packing group ш Description UN2811, Toxic solid, organic, n.o.s., 6.1, III 14.5 Environmental hazards Yes 14.6 Special precautions for user **Special Provisions** A3, A5 **ERG Code** 6L IMDG

Notes

- 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 **Environmental hazards** 14.6 Special precautions for user
- **Special Provisions** EmS-No 14.7 Maritime transport in bulk
- according to IMO instruments

RID

Notes

- 14.1 UN number or ID number
- 14.2 UN proper shipping name
- 14.3 Transport hazard class(es)
- 14.4 Packing group

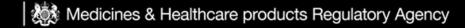
No components found suitable for Technical Name.

UN2811 Toxic solid, organic, n.o.s. 6.1 Ш UN2811, Toxic solid, organic, n.o.s., 6.1, III, Marine pollutant Ρ Yes 223, 274

F-A, S-A No information available No information available

No components found suitable for Technical Name.

- UN2811
- Toxic solid, organic, n.o.s. 6.1
- Ш





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Description 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions Classification code	UN2811, Toxic solid, organic, n.o.s., 6.1, III, Environmentally Hazardous Yes 274, 614 T2
ADR Notes 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	No components found suitable for Technical Name. UN2811 Toxic solid, organic, n.o.s. 6.1 III UN2811, Toxic solid, organic, n.o.s., 6.1, III, (E), Environmentally Hazardous Yes 274, 614 T2 (E)

SECTION 15: Regulatory information

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

National regulations

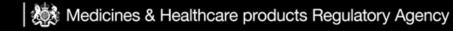
Germany

Water hazard class (WGK)

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).





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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 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

Dangerous substance category per Seveso Directive (2012/18/EU)

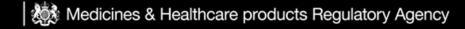
E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

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

Not applicable

International Inventories TSCA

DSL/NDSL EINECS/ELINCS ENCS Complies under research and development exemption or is regulated by a different government agency. Contact supplier for inventory compliance status Contact supplier for inventory compliance status Contact supplier for inventory compliance status





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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

- H301 Toxic if swallowed
- H361 Suspected of damaging fertility or 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

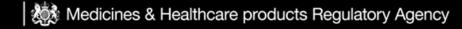
SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

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

STEL * STEL (Short Term Exposure Limit) Skin designation

Classification procedure		
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used	
Acute oral toxicity	Calculation method	
Acute dermal toxicity	Calculation method	
Acute inhalation toxicity - gas	Calculation method	
Acute inhalation toxicity - Vapour	Calculation method	
Acute inhalation toxicity - dust/mist	Calculation method	





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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

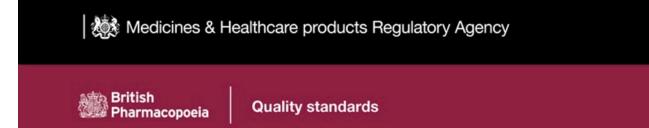
Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

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

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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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