

## 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 22-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 503  
**Product Name** Pilocarpine nitrate Assay Standard  
**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)** 205-723-7  
**CAS No.** 148-72-1  
**Chemical name** Pilocarpine nitrate  
**Pure substance/mixture** Substance  
**Formula** C<sub>11</sub>H<sub>17</sub>N<sub>3</sub>O<sub>5</sub>  
**Molecular weight** 271.27

#### 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

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

Acute toxicity - Oral	Category 2 - (H300)
Acute toxicity - Inhalation (Dusts/Mists)	Category 2 - (H330)

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### 2.2. Label elements

Contains Pilocarpine nitrate



**Signal word**  
Danger

#### Hazard statements

H300 - Fatal if swallowed  
H330 - Fatal if inhaled

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

P260 - Do not breathe dust/fume/gas/mist/vapours/spray  
P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing  
P310 - Immediately call a POISON CENTER or doctor  
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

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

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

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Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Pilocarpine nitrate 148-72-1	100	-	205-723-7	Acute Tox. 2 (H300) Acute Tox. 2 (H330)			

### 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 (ATE<sub>mix</sub>) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Pilocarpine nitrate 148-72-1	911	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  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>General advice</b>	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.

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Ingestion	Get immediate medical attention. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms	Coughing and/ or wheezing. Difficulty in breathing.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
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Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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### 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.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

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Personal precautions	Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not breathe dust. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.
<b><u>6.2. Environmental precautions</u></b>	
Environmental precautions	Prevent further leakage or spillage if safe to do so. Should not be released into the environment. Do not allow to enter into soil/subsoil. Prevent product from entering drains.
<b><u>6.3. Methods and material for containment and cleaning up</u></b>	
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.
<b><u>6.4. Reference to other sections</u></b>	
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 breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.
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. Do not breathe dust. Take off contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended.

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### 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. Store locked up. 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.

#### 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 (PNEC)

No information available.

### 8.2. Exposure controls

#### Personal protective equipment

##### Eye/face protection

Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

##### Hand protection

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

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Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective nitrile rubber gloves		

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**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. Do not breathe dust. Take off contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended.

**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	Crystalline powder
Colour	white
Odour	No information available.
Odour threshold	No information available

Property	Values	Remarks • Method
Melting point / freezing point	169 - 173 °C	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known



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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	Soluble in water 250 g/L	None known
Solubility(ies)	DMSO, Methanol, slightly soluble	
Partition coefficient	No data available	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	271.27
Molecular formula	C11H17N3O5

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.

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#### 10.4. Conditions to avoid

Conditions to avoid Excessive heat.

#### 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. Fatal if inhaled. (based on components).
Eye contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

##### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

##### Numerical measures of toxicity

Acute toxicity

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#### 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.

**Respiratory or skin sensitisation** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

**Reproductive toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

#### 11.2. Information on other hazards

##### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

##### 11.2.2. Other information

**Other adverse effects** No information available.

### SECTION 12: Ecological information

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#### 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 products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

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### SECTION 14: Transport information

#### IATA

14.1 UN number or ID number	UN1544
14.2 UN proper shipping name	Alkaloid salts, solid, n.o.s. (poisonous) (Pilocarpine nitrate)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	II
Description	UN1544, Alkaloid salts, solid, n.o.s. (poisonous) (Pilocarpine nitrate), 6.1, II
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	A3, A5, A6, A801
ERG Code	6L

#### IMDG

14.1 UN number or ID number	UN1544
14.2 UN proper shipping name	Alkaloids, solid, n.o.s. (poisonous) (Pilocarpine nitrate)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	II
Description	UN1544, Alkaloids, solid, n.o.s. (poisonous) (Pilocarpine nitrate), 6.1, II
14.5 Marine pollutant	NP
14.6 Special precautions for user	
Special Provisions	43, 274
EmS-No.	F-A, S-A No information available
14.7 Maritime transport in bulk according to IMO instruments	No information available

#### RID

14.1 UN number or ID number	UN1544
14.2 UN proper shipping name	Alkaloids, solid, n.o.s. (poisonous) (Pilocarpine nitrate)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	II
Description	UN1544, Alkaloids, solid, n.o.s. (poisonous) (Pilocarpine nitrate), 6.1, II
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	43, 274
Classification code	T2

#### ADR

14.1 UN number or ID number	UN1544
14.2 UN proper shipping name	Alkaloids, solid, n.o.s. (poisonous) (Pilocarpine nitrate)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	II
Description	UN1544, Alkaloids, solid, n.o.s. (poisonous) (Pilocarpine nitrate), 6.1, II, (D/E)

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14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	43, 274
Classification code	T2
Tunnel restriction code	(D/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). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the

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management of packaging and packaging waste, Journal of Laws 2013, item 888).  
Government statement of September 24, 2002 - European Agreement on the  
International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194,  
item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

### Persistent Organic Pollutants

Not applicable

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

H2 - ACUTE TOXIC

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

Not applicable

### International Inventories

#### TSCA

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.

#### DSL/NDSL

#### EINECS/ELINCS

#### ENCS

#### IECSC

#### KECL

#### PICCS

Contact supplier for inventory compliance status  
Contact supplier for inventory compliance status  
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AIIC

Contact supplier for inventory compliance status

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - 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

H300 - Fatal if swallowed

H330 - Fatal if inhaled

#### 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

Sk\*

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



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Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
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

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

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**End of Safety Data Sheet**