



# 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 11-Oct-2024

Revision Number 2

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

### 1.1. Product identifier

**Product Code(s)** CAT 788  
**Product Name** Ergocalciferol  
**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)** 200-014-9  
**CAS No.** 50-14-6  
**Chemical name** Ergocalciferol  
**Pure substance/mixture** Substance  
**Formula** C<sub>28</sub> H<sub>44</sub> O  
**Molecular weight** 396.72

### 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 - Dermal	Category 3 - (H311)



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Acute toxicity - Inhalation (Dusts/Mists)	Category 2 - (H330)
Reproductive toxicity	Category 2 - (H361)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity — repeated exposure	Category 1 - (H372)

### 2.2. Label elements

200-014-9  
Contains Ergocalciferol



**Signal word**  
Danger

### Hazard statements

H300 - Fatal if swallowed  
H311 - Toxic in contact with skin  
H330 - Fatal if inhaled  
H361 - Suspected of damaging fertility or the unborn child  
H362 - May cause harm to breast-fed children  
H372 - Causes damage to organs through prolonged or repeated exposure

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

P260 - Do not breathe dust/fume/gas/mist/vapours/spray  
P263 - Avoid contact during pregnancy and while nursing  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
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

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.



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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
Ergocalciferol	-	-

### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

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)
Ergocalciferol 50-14-6	100	-	200-014-9 (603-179-00-9)	Acute Tox. 2 (H330) Acute Tox. 2 (H300) Acute Tox. 3 (H311) Repr. 2 (H361) Lact. (H362) STOT RE 1 (H372)			

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

#### Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (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
Ergocalciferol 50-14-6	10	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



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### 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>	Get immediate medical attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
<b>Skin contact</b>	Get immediate medical attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Ingestion</b>	Get immediate medical attention. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person.
<b>Self-protection of the first aider</b>	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

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

<b>Note to doctors</b>	Treat symptomatically.
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## **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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<b>Large Fire</b>	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.

### 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. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid generation of dust. Do not breathe dust. 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.

### 6.2. Environmental precautions

**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.

### 6.3. Methods and material for containment 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.



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## 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. Take off contaminated clothing and wash it before reuse. 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. 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. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace.

### 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.

#### **Biological occupational exposure limits**



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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 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. Wear protective nitrile rubber gloves. Wear suitable gloves. Impervious gloves.

##### Skin and body protection

Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

##### 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. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace.

#### 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**

Powder

**Appearance**

Crystalline powder



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Colour	white to orange brown
Odour	Odourless.
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	115 - 118 °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
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	Insoluble in water 50 mg/L	None known
Solubility(ies)	No data available	None known
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	396.72
Molecular formula	C <sub>28</sub> H <sub>44</sub> O

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



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### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

#### Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

### 10.4. Conditions to avoid

Conditions to avoid Excessive heat.

### 10.5. Incompatible materials

Incompatible materials None known based on information supplied.

### 10.6. Hazardous decomposition products

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.



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**Skin contact** Specific test data for the substance or mixture is not available. Toxic in contact with skin. (based on components).

**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

#### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ergocalciferol	= 10 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.

**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



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the unborn child.

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

**STOT - repeated exposure** Causes damage to organs through prolonged or repeated exposure.

**Aspiration hazard** No information available.

### 11.2. Information on other hazards

#### 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** 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.



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### 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.

## SECTION 14: Transport information

### IATA

14.1 UN number or ID number	UN2811
14.2 UN proper shipping name	Toxic solid, organic, n.o.s. (Ergocalciferol)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	II
Description	UN2811, Toxic solid, organic, n.o.s. (Ergocalciferol), 6.1, II
14.5 Environmental hazards	No
14.6 Special precautions for user	
Special Provisions	A3, A5
ERG Code	6L

### IMDG

14.1 UN number or ID number	UN2811
14.2 UN proper shipping name	Toxic solid, organic, n.o.s. (Ergocalciferol)
14.3 Transport hazard class(es)	6.1
14.4 Packing group	II



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<b>Description</b>	UN2811, Toxic solid, organic, n.o.s. (Ergocalciferol), 6.1, II
<b>14.5 Marine pollutant</b>	NP
<b>Environmental hazards</b>	No
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	274
<b>EmS-No.</b>	F-A, S-A No information available
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	No information available

### RID

<b>14.1 UN number or ID number</b>	UN2811
<b>14.2 UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Ergocalciferol)
<b>14.3 Transport hazard class(es)</b>	6.1
<b>14.4 Packing group</b>	II
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s. (Ergocalciferol), 6.1, II
<b>14.5 Environmental hazards</b>	No
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	274, 614
<b>Classification code</b>	T2

### ADR

<b>14.1 UN number or ID number</b>	UN2811
<b>14.2 UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Ergocalciferol)
<b>14.3 Transport hazard class(es)</b>	6.1
<b>14.4 Packing group</b>	II
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s. (Ergocalciferol), 6.1, II, (D/E)
<b>14.5 Environmental hazards</b>	No
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	274, 614
<b>Classification code</b>	T2
<b>Tunnel restriction code</b>	(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)



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### 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
Ergocalciferol - 50-14-6	75	

### Persistent Organic Pollutants

Not applicable

### Export Notification requirements

This product contains substances which are regulated pursuant to Regulation (EC) No. 649/2012 of the European parliament and of the council concerning the export and import of dangerous chemicals

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Ergocalciferol - 50-14-6	I.1

### 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, to the best of its ability, has confirmed that the chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb 2019, as amended Feb 2021."



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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
AIC	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

- H300 - Fatal if swallowed  
H311 - Toxic in contact with skin  
H330 - Fatal if inhaled  
H361 - Suspected of damaging fertility or the unborn child  
H362 - May cause harm to breast-fed children  
H372 - Causes damage to organs through prolonged or repeated exposure

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

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



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



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World Health Organization

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

### Disclaimer

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**End of Safety Data Sheet**