

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 07-May-2024 Revision Number 2

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

1.1. Product identifier

Product Code(s) CAT 687

Product Name Tioconazole impurity standard

Form Not applicable

Pure substance/mixture Mixture

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

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		

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Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

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

Acute toxicity - Oral	Category 4 - (H302)
Skin sensitisation	Category 1 - (H317)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)

2.2. Label elements

Contains Tioconazole



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Signal word

Warning

Hazard statements

H302 - Harmful if swallowed

H317 - May cause an allergic skin reaction

H410 - Very toxic to aquatic life with long lasting effects

EUH208 - Contains 1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole Hydrochloride May produce an allergic reaction.

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

P264 - Wash face, hands and any exposed skin thoroughly after handling

P273 - Avoid release to the environment

P280 - Wear protective gloves

P391 - Collect spillage

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

No information available.

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

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

Endocrine Disraptor information This prod	idet dees not contain any known or suspe	etea chaochne aisraptors.
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
Tioconazole Impurity C	-	•
1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl	-	-
)methoxy]ethyl]-1H-imidazole Hydrochloride		
1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(2,5-dichlorot	-	-
hiophen-3-yl)methoxy]ethyl]-1H-imidazole		
Hydrochloride		
(1RS)-1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl	-	-
)ethanol		

SECTION 3: Composition/information on ingredients

3.1 Substances

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Not applicable

3.2 Mixtures

Chemical nature

Mixture of organic compounds.

	Weight-%	REACH registration number	`	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Tioconazole Impurity C 119386-76-4	0.1 - 1	-	-	Acute Tox. 4 (H302)			
1-[(2RS)-2-(2,4-Dich lorophenyl)-2-[(thiop hen-3-yl)methoxy]et hyl]-1H-imidazole Hydrochloride 61709-33-9		-	•	Acute Tox. 4 (H302) Skin Sens. 1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			
1-[(2RS)-2-(2,4-Dich lorophenyl)-2-[(2,5-d ichlorothiophen-3-yl) methoxy]ethyl]-1H-i midazole Hydrochloride 61675-62-5		-	1	Acute Tox. 4 (H302)			
(1RS)-1-(2,4-Dichlor ophenyl)-2-(1H-imid azol-1-yl)ethanol 24155-42-8		-	246-042-5	Acute Tox. 3 (H301) Eye Irrit. 2 (H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			

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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

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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 contactRinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a doctor.

Skin contact Wash with soap and water. May cause an allergic skin reaction. 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. Call a doctor.

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

Symptoms Itching. Rashes. Hives.

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

Note to doctorsMay cause sensitisation in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo 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

Product is or contains a sensitiser. May cause sensitisation by skin contact.

5.3. Advice for firefighters

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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. Keep people away

from and upwind of spill/leak.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 upTake 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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. 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

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product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's ce

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

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)
Predicted No Effect Concentration
(PNEC)

No information available. 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

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89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves. Wear

suitable gloves.

Skin and body protectionWear 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.

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
Colour white

Odour No information available.
Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownInitial boiling point and boiling rangeNo data availableNone knownFlammabilityNo data availableNone knownFlammability Limit in AirNone 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

pH (as aqueous solution)No data availableNo informationKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone knownWater solubilityNo data availableNone known

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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 No data available **Liquid Density** No data available

Relative vapour density None known

Particle characteristics

No information available **Particle Size Particle Size Distribution** No information available

9.2. Other information

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

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge

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

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Incompatible materialsNone 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 May cause sensitisation by skin contact. Specific test data for the substance or mixture is

not available. Repeated or prolonged skin contact may cause allergic reactions with

susceptible persons. (based on components).

Ingestion Specific test data for the substance or mixture is not available. Harmful if swallowed. (based

on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

 ATEmix (oral)
 785.70 mg/kg

 ATEmix (dermal)
 99,999.00 mg/kg

 ATEmix (inhalation-gas)
 99,999.00 ppm

 ATEmix (inhalation-dust/mist)
 99,999.00 mg/l

 ATEmix (inhalation-vapour)
 99,999.00 mg/l

Component Information

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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 May cause an allergic skin reaction.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposureNo 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 Very toxic to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient	
(1RS)-1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl)ethanol	2.36	

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment	
(1RS)-1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl)ethanol	The substance is not PBT / vPvB	

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

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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 UN3077

14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride)

14.3 Transport hazard class(es)

14.4 Packing group

Description

UN3077, Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride), 9, III

14.5 Environmental hazards

14.6 Special precautions for user

Special Provisions

A97, A158, A179, A197, A215

ERG Code

Ш

Ρ

Yes

Yes

IMDG

14.1 UN number or ID number

14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride)

14.3 Transport hazard class(es)

14.4 Packing group

Description

9

UN3077, Environmentally hazardous substances, solid, n.o.s. (Tioconazole, 1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride), 9, III, Marine pollutant

14.5 Marine pollutant

Environmental hazards

14.6 Special precautions for user

Special Provisions

EmS-No.

274, 335, 966, 967, 969

F-A, S-F No information available

14.7 Maritime transport in bulk according to IMO instruments

No information available

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RID

UN3077 14.1 UN number or ID number

14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride) 9

14.3 Transport hazard class(es)

14.4 Packing group

Description

UN3077, Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride), 9, III

14.5 Environmental hazards

14.6 Special precautions for user

Special Provisions

Classification code

274, 335, 375, 601

M7

Yes

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ADR

14.1 UN number or ID number UN3077

14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride)

14.3 Transport hazard class(es)

14.4 Packing group

Description

Ш

Yes

UN3077, Environmentally hazardous substances, solid, n.o.s. (Tioconazole,

1-[(2RS)-2-(2,4-Dichlorophenyl)-2-[(thiophen-3-yl)methoxy]ethyl]-1H-imidazole

Hydrochloride), 9, III, (-)

14.5 Environmental hazards

14.6 Special precautions for user

Special Provisions Classification code 274, 335, 601, 375

M7 **Tunnel restriction code** (-)

SECTION 15: Regulatory information

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

National regulations

Germany

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

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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

Persistent Organic Pollutants

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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 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
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
IECSC
Contact supplier for inventory compliance status
KECL
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
AllC
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

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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

H302 - Harmful if swallowed

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

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 STEL (Short Term Exposure Limit)

Ceiling Maximum limit value Sk* Skin designation

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

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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

Revision date

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End of Safety Data Sheet

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