



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-May-2025

Revision Number 1.01

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

1.1. Product identifier

Product Code(s) CAT 1046
Product Name timolol maleate
Form Not applicable

REACH registration number -

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

Substance Name Timolol Maleate
EC No (EU Index No) 248-111-5
CAS No. 26921-17-5
Pure substance/mixture Substance
Formula C₁₃ H₂₄ N₄ O₃ . C₄ H₄ O₄
Molecular weight 432.55

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



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



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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)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity (repeated exposure)	Category 1 - (H372)

2.2. Label elements

248-111-5
Contains Timolol maleate



Signal word

Danger

Hazard statements

H302 - Harmful if swallowed.
H361 - Suspected of damaging fertility or the unborn child.
H372 - Causes damage to organs through prolonged or repeated exposure.

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

P201 - Obtain special instructions before use
P260 - Do not breathe dust, fume, gas, mist, vapors and spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves, protective clothing, eye protection and face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable



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2.3. Other hazards

No information available.

PBT & vPvB

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
Timolol maleate	-	-

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)	Notes
Timolol maleate 26921-17-5	100	-	248-111-5	Acute Tox. 4 (H302) Repr. 2 (H361) 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_{mix}) 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
Timolol maleate 26921-17-5	1028	No data available	No data available	No data available	No data available



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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

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. Call a doctor.

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

Symptoms	No information available.
Effects of Exposure	May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility. Causes damage to organs through prolonged or repeated exposure.

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.
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.

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 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

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



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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. Store locked up.

Storage class (TRGS 510)

LGK 6.1C.

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) - Workers No information available

Derived No Effect Level (DNEL) - General Public No information available.

Predicted No Effect Concentration (PNEC) No information available.



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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.
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

Appearance	Solid
Physical state	Solid
Colour	white, to, off-white
Odour	No information available
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	196 °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	



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Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
SADT (°C)	No data available	None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Soluble in water	None known
Solubility(ies)	DMSO Ethanol Methanol	
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 formula	C ₁₃ H ₂₄ N ₄ O ₃ . C ₄ H ₄ O ₄
Molecular weight	432.55

9.2.1. Information with regards to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	No information available.
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10.2. Chemical stability

Stability	Stable under normal conditions.
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Explosion data

Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.



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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.

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

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. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

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

Acute toxicity Harmful if swallowed.

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Timolol maleate	= 1028 mg/kg (Rat)	-	-



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Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	Based on available data, the classification criteria are not met.
11.2. Information on other hazards	
11.2.1. Endocrine disrupting properties	
Endocrine disrupting properties	Based on available data, the classification criteria are not met.
11.2.2. Other information	
Other adverse effects	No information available.



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SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Timolol maleate	-	LC50: = 411 mg/L (96h, Pimephales promelas)	-	EC50: =161 mg/L (48h, Daphnia magna)

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 Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

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	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

ADN

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated



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14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special precautions for user	
Special Provisions	None

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)
Chemical Prohibition Ordinance (ChemVerbotsV) This product is subject to requirements and restrictions regarding handling and delivery

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable
Storage of Hazardous Material SC 11/13
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Class B
Major Accidents Ordinance SR 814.012 Not applicable

European Union

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

Authorisations and/or restrictions on use:

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

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

Not applicable



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Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 2024/590

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., FFDC, 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

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 Chemicals Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

H302 - Harmful if swallowed

H361 - Suspected of damaging fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

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

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P314 - Get medical advice/attention if you feel unwell

Legend

ACGIH	American Conference of Governmental Industrial Hygienists
AIDII	Italian Association of Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AiIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CLP	Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DFG	German Research Foundation
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EC Number	European Community number
EmS	Emergency Schedule



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ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
EWC	European Waste Codes
GHS	Globally Harmonized System
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organisation
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organisation for Standardisation
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MAL	Measuring Technical Hygienic Air Needs
MARPOL	International Convention for the Prevention of Pollution from Ships
MDLPS	Ministry of Labour and Social Policy
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure



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SVHC	Substance of very high concern
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TRGS	Technical Rule for Hazardous Substances
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
Sen+	Sensitiser
Sk*	Skin designation
**	Hazard 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
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)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)



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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)
National Institute of Technology and Evaluation (NITE)
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)
U.S. 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

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End of Safety Data Sheet