

# 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 25-Jun-2025

Revision Number 2

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

### 1.1. Product identifier

Product Code(s) CAT 1077

Product Name melatonin

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 Melatonin

EC No. (Index No.) 200-797-7

CAS No. 73-31-4

Pure substance/mixture Substance

Formula  $C_{13}H_{16}N_2O_2$

Molecular weight 232.28

### 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]

Reproductive toxicity	Category 2 - (H361)
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### 2.2. Label elements

Contains Melatonin



**Signal word**  
Warning

### Hazard statements

H361 - Suspected of damaging fertility or the unborn child.

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

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

### 2.3. Other hazards

No information available.

**PBT & vPvB**

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

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**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
Melatonin	-	-

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)	Notes
Melatonin 73-31-4	100	-	200-797-7	Repr. 2 (H361)	-	-	-	-

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

#### Acute Toxicity Estimate

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

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Melatonin 73-31-4	3200	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

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	Rinse mouth.

## 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.

## 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.
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.
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### 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** 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

**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

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## 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.

## Storage class (TRGS 510)

LGK 11.

## 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.

### 8.2. Exposure controls

#### Personal protective equipment

##### Eye/face protection

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

##### Hand protection

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

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<b>Skin and body protection</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	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.
<b>Environmental exposure controls</b>	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

<b>Appearance</b>	Powder
<b>Physical state</b>	Solid
<b>Colour</b>	off-white, white, to, light brown
<b>Odour</b>	No information available
<b>Odour threshold</b>	No information available

<b>Property</b>	<b>Values</b>	<b>Remarks • Method</b>
<b>Melting point / freezing point</b>	116 - 118 °C	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>SADT (°C)</b>	No data available	None known
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	slightly soluble Chloroform Methanol	



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Partition coefficient	1.6	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	C13 H16 N2 O2
Molecular weight	232.28

#### 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.

### 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	None known based on information supplied.
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### 10.5. Incompatible materials

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**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.

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

**Numerical measures of toxicity**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Melatonin	> 3200 mg/kg ( Rat )	-	-

**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.

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

**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.

## **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**

Chemical name

Partition coefficient

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Melatonin	1.6
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## 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.

## 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 |
|-----------------------------|---------------|

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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
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

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## Germany

Water hazard class (WGK)

obviously hazardous to water (WGK 2)

Chemical Prohibition Ordinance  
(ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Not applicable

Storage of Hazardous Material

Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Not applicable

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

## Persistent Organic Pollutants

Not applicable

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

Not applicable

## International Inventories

TSCA

U.S. INVENTORY (TSCA): Not listed on inventory. For purposes of 40 CFR 720.36, this

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DSL/NDL	product is for Research and Development (R&D) Use Only
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
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 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

## 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

H361 - Suspected of damaging fertility or the unborn child  
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  
P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

#### 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)

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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
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



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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
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

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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)  
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

Revision date 25-Jun-2025

Reason for revision Classification Physical and chemical properties Gloves Material

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

### Disclaimer

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## SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-Jun-2025

Revision Number 2

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**End of Safety Data Sheet**