

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 18-Apr-2023

Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 1295
Product Name Metformin Impurity D
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) 203-615-4
CAS No 108-78-1
Chemical name Melamine
Pure substance/mixture Substance
Formula C₃H₆N₆
Molecular weight 126.12

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

Regulation (EC) No 1272/2008

| | |
|---|---------------------|
| Acute toxicity - Dermal | Category 4 - (H312) |
| Acute toxicity - Inhalation (Dusts/Mists) | Category 4 - (H332) |
| Carcinogenicity | Category 2 - (H351) |
| Reproductive toxicity | Category 2 - (H361) |

2.2. Label elements

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Contains Melamine



Signal word
Warning

Hazard statements

H312 - Harmful in contact with skin
H332 - Harmful if inhaled
H351 - Suspected of causing cancer
H361f - Suspected of damaging fertility

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

P201 - Obtain special instructions before use
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P312 - Call a POISON CENTER or doctor if you feel unwell
P321 - Specific treatment (see supplemental first aid instructions on this label)
P501 - Dispose of contents/ container to an approved waste disposal plant

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.

| 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 |
|---------------|---|--|
| Melamine | - | - |

SECTION 3: Composition/information on ingredients

3.1 Substances

| Chemical name | Weight-% | REACH registration | EC No (EU | Classification according | Specific | M-Factor | M-Factor |
|---------------|----------|--------------------|-----------|--------------------------|----------|----------|----------|
|---------------|----------|--------------------|-----------|--------------------------|----------|----------|----------|

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| | | number | Index No) | to Regulation (EC) No. 1272/2008 [CLP] | concentration limit (SCL) | | (long-term) |
|----------------------|--------------|--------|-----------|---|------------------------------|--|-------------|
| Melamine 108-78-1 | 90 - 100% | - | 203-615-4 | Acute Tox. 4 (H312) Acute Tox. 4 (H332) Carc. 2 (H351) Repr. 2 (H361f) | | | |

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 |
|----------------------|-----------------|----------------------|--|---|---|
| Melamine 108-78-1 | 3161 | 1000 | No data available | No data available | No data available |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---|--|
| General advice | Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention. |
| Inhalation | If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. If symptoms persist, call a doctor. |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor. |
| Skin contact | Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a doctor. |
| Ingestion | Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get medical attention. |
| Self-protection of the first aider | Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid breathing |

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dust/fume/gas/mist/vapours/spray. Use personal protective equipment as required. See section 8 for more information.

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

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

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

Note to doctors Treat symptomatically.

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.

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. Avoid generation of dust. Do not breathe dust.

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

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Environmental precautions Prevent further leakage or spillage if safe to do so.

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. Ensure adequate ventilation. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid generation of dust.

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. Avoid breathing dust/fume/gas/mist/vapours/spray.

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. Store locked up. 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

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Exposure Limits

| Chemical name | Ireland | Italy | Italy REL | Latvia | Lithuania |
|----------------------|---------|-------|-----------|--------|----------------------------|
| Melamine 108-78-1 | - | - | - | - | TWA: 0.5 mg/m ³ |

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

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

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

Skin and body protection Wear suitable protective clothing. Long sleeved 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. Avoid breathing dust/fume/gas/mist/vapours/spray.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------|---------------------------|
| Physical state | Solid |
| Appearance | Crystalline powder |
| Colour | white |
| Odour | No information available. |
| Odour threshold | No information available |

| Property | Values | Remarks • Method |
|---|---------------------------|--------------------------|
| Melting point / freezing point | 350 °C | None known |
| Initial boiling point and boiling range | 354 °C | 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 | 300 °C | None known |
| Autoignition temperature | > 400 °C | None known |
| Decomposition temperature | 354 °C | 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 | Soluble in water 3.48 g/L | None known |
| Solubility(ies) | DMSO, slightly soluble | |
| Partition coefficient | -1.22 | None known |
| Vapour pressure | 0.000000000035 kPa | None known |
| Relative density | 1.57 g/cm ³ | None known |
| Bulk density | 1573 kg/m ³ | |
| 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 | 126.12 |
| Molecular formula | C ₃ H ₆ N ₆ |

9.2.1. Information with regards to physical hazard classes
Not applicable 354 °C 354 °C

9.2.2. Other safety characteristics
No information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Excessive heat.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. Harmful by inhalation. (based on components).

Eye contact Specific test data for the substance or mixture is not available.

Skin contact May be absorbed through the skin in harmful amounts. Harmful in contact with skin. (based on components).

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Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing.

Numerical measures of toxicity

Acute toxicity

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|----------------------|-------------------------|--------------------------------|
| Melamine | = 3161 mg/kg (Rat) | > 1000 mg/kg (Rabbit) | = 3248 mg/m ³ (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 Contains a known or suspected carcinogen. Classification based on data available for ingredients. Suspected of causing cancer.

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 No information available.

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STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|---------------|--|--|----------------------------|--------------------------------------|
| Melamine | EC50: =940mg/L (96h, Scenedesmus pannonicus) | LC50: >3000mg/L (96h, Poecilia reticulata) | - | EC50: >2000mg/L (48h, Daphnia magna) |

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 |
|---------------|-----------------------|
| Melamine | -1.22 |

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

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PBT and vPvB assessment The product contains substance(s) classified as PBT or vPvB.

| Chemical name | PBT and vPvB assessment |
|---------------|---|
| Melamine | The substance is not PBT / vPvB PBT assessment does not apply |

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 | 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 Marine pollutant | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None No information available |
| 14.7 Maritime transport in bulk | No information available |

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according to IMO instruments

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 |

SECTION 15: Regulatory information

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

Water hazard class (WGK) slightly hazardous to water (WGK 1)

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

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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

Not applicable

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

Not applicable

International Inventories

TSCA

Complies

DSL/NDL

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

AIIC

Contact supplier for inventory compliance status

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Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H312 - Harmful in contact with skin
H332 - Harmful if inhaled
H351 - Suspected of causing cancer
H361f - Suspected of damaging fertility

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 * 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 |

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| | |
|--------------------------|--------------------|
| Carcinogenicity | Calculation method |
| STOT - single exposure | Calculation method |
| STOT - repeated exposure | Calculation method |
| Acute aquatic toxicity | Calculation method |
| Chronic aquatic toxicity | Calculation method |
| Aspiration hazard | Calculation method |
| Ozone | Calculation method |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AELG(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 18-Apr-2023

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

Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

End of Safety Data Sheet