

SAFETY DATA SHEET

according to the Globally Harmonized System



Albendazole Sulfoxide (10%) Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
3884320-00021

Date of last issue: 28.09.2024
Date of first issue: 30.11.2018

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Albendazole Sulfoxide (10%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - : Category 2 (Gastrointestinal tract, Central nervous system)
single exposure (Oral)

Specific target organ toxicity - : Category 2 (Gastrointestinal tract, Central nervous system,
repeated exposure (Oral) Immune system, Liver)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

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Albendazole Sulfoxide (10%) Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 5.0 | Revision Date: 14.04.2025 | SDS Number: 3884320-00021 | Date of last issue: 28.09.2024 Date of first issue: 30.11.2018 |
|----------------|------------------------------|------------------------------|---|

| | | |
|--------------------------|---|--|
| Hazard pictograms | : | |
| Signal word | : | Warning |
| Hazard statements | : | <p>H317 May cause an allergic skin reaction. H361d Suspected of damaging the unborn child. H371 May cause damage to organs (Gastrointestinal tract, Central nervous system) if swallowed. H373 May cause damage to organs (Gastrointestinal tract, Central nervous system, Immune system, Liver) through prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects.</p> |
| Precautionary statements | : | <p>Prevention: P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe mist or vapours. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>Response: P302 + P352 IF ON SKIN: Wash with plenty of water. P308 + P316 IF exposed or concerned: Get emergency medical help immediately. P333 + P317 If skin irritation or rash occurs: Get medical help. P362 + P364 Take off contaminated clothing and wash it before reuse. P391 Collect spillage.</p> <p>Storage: P405 Store locked up.</p> <p>Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.</p> |

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|-----------------------|------------|-----------------------|
| Albendazole Sulfoxide | 54029-12-8 | >= 10 - < 20 |

SAFETY DATA SHEET

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| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 5.0 | Revision Date: 14.04.2025 | SDS Number: 3884320-00021 | Date of last issue: 28.09.2024 Date of first issue: 30.11.2018 |
|----------------|------------------------------|------------------------------|---|

4. FIRST AID MEASURES

| | |
|---|---|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. |
| If swallowed | : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : May cause an allergic skin reaction. Suspected of damaging the unborn child. May cause damage to organs if swallowed. May cause damage to organs through prolonged or repeated exposure if swallowed. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : Treat symptomatically and supportively. |

5. FIREFIGHTING MEASURES

| | |
|---------------------------------------|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during fire-fighting | : Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : Carbon oxides Nitrogen oxides (NO _x) Sulphur oxides |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |

SAFETY DATA SHEET

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Albendazole Sulfoxide (10%) Formulation

Version
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Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types: Strong oxidizing agents

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|-----------------------|------------|-------------------------------------|--|----------|
| Albendazole Sulfoxide | 54029-12-8 | TWA | 45 µg/m ³ (OEB 3) | Internal |
| | | Further information: DSEN | | |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

Engineering measures

- : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

| | |
|--------------------------|--|
| Respiratory protection | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | |
| Hand protection | : Combined particulates and organic vapour type |
| Material | : Chemical-resistant gloves |
| Remarks | : Consider double gloving. |
| Eye protection | : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Hygiene measures | : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of |

SAFETY DATA SHEET

according to the Globally Harmonized System



Albendazole Sulfoxide (10%) Formulation

Version
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SDS Number:
3884320-00021

Date of last issue: 28.09.2024
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engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|-------------------|
| Appearance | : | suspension |
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | Not applicable |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |

SAFETY DATA SHEET

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Version 5.0 Revision Date: 14.04.2025 SDS Number: 3884320-00021 Date of last issue: 28.09.2024
Date of first issue: 30.11.2018

| | | |
|--------------------------|---|--|
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | : | |
| Particle size | : | No data available |

10. STABILITY AND REACTIVITY

| | | |
|------------------------------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

11. TOXICOLOGICAL INFORMATION

| | | |
|--|---|--------------|
| Information on likely routes of exposure | : | Inhalation |
| | : | Skin contact |
| | : | Ingestion |
| | : | Eye contact |

Acute toxicity

Not classified based on available information.

Product:

| | | |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 5,000 mg/kg |
| | : | Method: Calculation method |

Components:

Albendazole Sulfoxide:

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Mouse): 1,500 mg/kg |
| | : | LD50 (Rat): 2,400 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 265 mg/kg Application Route: Intravenous |

Skin corrosion/irritation

Not classified based on available information.

Components:

Albendazole Sulfoxide:

SAFETY DATA SHEET

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| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|-----------------|---|--|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Assessment | : | Probability or evidence of low to moderate skin sensitisation rate in humans |
| Result | : | positive |
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Result | : | Sensitiser |

Germ cell mutagenicity

Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | | Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Result: negative |

Carcinogenicity

Not classified based on available information.

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5.0

Revision Date:
14.04.2025

SDS Number:
3884320-00021

Date of last issue: 28.09.2024
Date of first issue: 30.11.2018

Components:

Albendazole Sulfoxide:

| | | |
|-------------------|---|-----------------------|
| Species | : | Mouse |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| NOAEL | : | 400 mg/kg body weight |
| Result | : | negative |

| | | |
|-------------------|---|----------------------|
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| NOAEL | : | 20 mg/kg body weight |
| Result | : | negative |

| | | |
|------------------------------|---|---|
| Carcinogenicity - Assessment | : | No evidence of carcinogenicity in animal studies. |
|------------------------------|---|---|

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Albendazole Sulfoxide:

| | | |
|----------------------|---|--|
| Effects on fertility | : | Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 30 mg/kg body weight Result: No effects on fertility |
|----------------------|---|--|

| | | |
|-------------------------------|---|--|
| Effects on foetal development | : | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations |
|-------------------------------|---|--|

| | | |
|--|---|--|
| | : | Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations, Maternal toxicity observed. |
|--|---|--|

| | | |
|--|---|---|
| | : | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 5.8 mg/kg body weight Result: Effects on postnatal development |
|--|---|---|

| | | |
|--|---|--|
| | : | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 7 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected. |
|--|---|--|

SAFETY DATA SHEET

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Albendazole Sulfoxide (10%) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 3884320-00021 Date of last issue: 28.09.2024
Date of first issue: 30.11.2018

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT - single exposure

May cause damage to organs (Gastrointestinal tract, Central nervous system) if swallowed.

Components:

Albendazole Sulfoxide:

Exposure routes : Oral
Target Organs : Gastrointestinal tract, Central nervous system
Assessment : May cause damage to organs.

STOT - repeated exposure

May cause damage to organs (Gastrointestinal tract, Central nervous system, Immune system, Liver) through prolonged or repeated exposure if swallowed.

Components:

Albendazole Sulfoxide:

Exposure routes : Oral
Target Organs : Gastrointestinal tract, Central nervous system, Immune system, Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Albendazole Sulfoxide:

Species : Rat
LOAEL : 168 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Gastrointestinal tract, Testis
Symptoms : Diarrhoea, Vomiting

Species : Dog
LOAEL : 48 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Gastrointestinal tract
Symptoms : Diarrhoea, Vomiting

Species : Mouse
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Blood, Liver, Nose
Symptoms : Hematologic effects, Liver effects

Species : Rat

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according to the Globally Harmonized System



Albendazole Sulfoxide (10%) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 3884320-00021 Date of last issue: 28.09.2024
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| | |
|-------------------|--|
| LOAEL | : ≥ 30 mg/kg |
| Application Route | : Oral |
| Exposure time | : 6 Months |
| Target Organs | : Blood |
| Symptoms | : Hematologic effects |
| Species | : Dog |
| LOAEL | : 40 mg/kg |
| Application Route | : Oral |
| Exposure time | : 6 Months |
| Target Organs | : Blood, Liver |
| Symptoms | : Hematologic effects, Liver effects |
| Species | : Rat |
| NOAEL | : 7 mg/kg |
| Application Route | : Oral |
| Exposure time | : 60 d |
| Target Organs | : Liver, Testis |
| Symptoms | : Liver effects, male reproductive effects |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Albendazole Sulfoxide:

| | |
|---------------------|--|
| General Information | : Symptoms: Allergic reactions, hair loss, Gastrointestinal disturbance, Headache, Dizziness |
| Skin contact | : Target Organs: Skin Symptoms: Allergic reactions Remarks: May cause sensitisation by skin contact. |
| Ingestion | : Target Organs: Gastrointestinal tract Symptoms: Gastrointestinal disturbance, Diarrhoea, Abdominal pain Target Organs: Central nervous system Symptoms: Headache, Dizziness Target Organs: Liver Symptoms: liver function change Target Organs: Immune system Symptoms: immune system effects |

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Albendazole Sulfoxide:

| | |
|-------------------------------|--|
| Toxicity to fish | : EC50 (Brachydanio rerio (zebrafish)): 0.042 mg/l Exposure time: 144 hrs |
| Toxicity to daphnia and other | : EC50 (Daphnia magna (Water flea)): 0.068 mg/l |

SAFETY DATA SHEET

according to the Globally Harmonized System



Albendazole Sulfoxide (10%) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 3884320-00021 Date of last issue: 28.09.2024
Date of first issue: 30.11.2018

| | |
|-------------------------------------|--|
| aquatic invertebrates | Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : EC50 (Raphidocelis subcapitata (freshwater green alga)): 0.024 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity) | : 10 |
| M-Factor (Chronic aquatic toxicity) | : 10 |

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Albendazole Sulfoxide:

| | |
|--|--------------------------|
| Partition coefficient: n-octanol/water | : log Pow: 1.27 pH: 7 |
|--|--------------------------|

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

| | |
|------------------------|---|
| Waste from residues | : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

| | |
|---------------------------|--|
| UN number | : UN 3082 |
| Proper shipping name | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Albendazole Sulfoxide) |
| Class | : 9 |
| Packing group | : III |
| Labels | : 9 |
| Environmentally hazardous | : yes |

SAFETY DATA SHEET

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Albendazole Sulfoxide (10%) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 3884320-00021 Date of last issue: 28.09.2024
Date of first issue: 30.11.2018

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Albendazole Sulfoxide)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Albendazole Sulfoxide)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Revision Date : 14.04.2025

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

SAFETY DATA SHEET

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Albendazole Sulfoxide (10%) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 3884320-00021 Date of last issue: 28.09.2024
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN