

Albendazole Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 10232227-00013 Date of last issue: 04.04.2023
Date of first issue: 16.11.2021

SECTION 1: IDENTIFICATION

Product name : Albendazole Formulation

Manufacturer or supplier's details

Company : MSD

Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

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

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

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : 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.

Albendazole Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 10232227-00013 Date of last issue: 04.04.2023
 Date of first issue: 16.11.2021

Precautionary statements

:

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 P264 Wash skin 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.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
 P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
 Contact with dust can cause mechanical irritation or drying of the skin.
 May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Albendazole Sulfoxide	54029-12-8	>= 30 -< 60
Cellulose	9004-34-6	>= 10 -< 30

SECTION 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

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

		of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	If in eyes, rinse well with water. 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. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
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.

SECTION 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	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO _x) Sulphur oxides Metal 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.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	2Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

- 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.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
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
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- 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.

Albendazole Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 10232227-00013 Date of last issue: 04.04.2023
 Date of first issue: 16.11.2021

- Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Albendazole Sulfoxide	54029-12-8	TWA	40 µg/m ³ (OEB 3)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm ²	Internal
Cellulose	9004-34-6	TWA	10 mg/m ³	AU OEL
		TWA	10 mg/m ³	ACGIH

- Engineering measures** : 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 : Particulates type
- Hand protection
- 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.

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder
Colour	: cream
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)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
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

Albendazole Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 10232227-00013 Date of last issue: 04.04.2023
Date of first issue: 16.11.2021

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 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 : LD50 (Rat): 265 mg/kg

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

Chronic toxicity

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

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

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 - Assess- : No evidence of carcinogenicity in animal studies.

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

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Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

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
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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
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	:	Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations, Maternal toxicity observed.
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	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 5.8 mg/kg body weight Result: Effects on postnatal development
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	:	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.
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Reproductive toxicity - Assessment	:	Suspected of damaging the unborn child.
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Cellulose:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion
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Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

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

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Blood, Liver, Nose
 Symptoms : Hematologic effects, Liver effects

Species : Rat
 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

Cellulose:

Species : Rat
 NOAEL : $\geq 9,000$ mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

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

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

Target Organs: Immune system
Symptoms: immune system effects

SECTION 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
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Raphidocelis subcapitata (freshwater green alga)):
plants : 0.024 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Persistence and degradability**Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential**Components:****Albendazole Sulfoxide:**

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

Mobility in soil

No data available

Other adverse effects

No data available

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

SECTION 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.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Albendazole Sulfoxide)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Albendazole Sulfoxide)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**ADG**

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Albendazole Sulfoxide)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	2Z
Environmentally hazardous	:	yes

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.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Prohibition/Licensing Requirements	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.
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The components of this product are reported in the following inventories:

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

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Revision Date	:	30.09.2023
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/

Date format	:	dd.mm.yyyy
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Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.

Albendazole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10232227-00013	Date of first issue: 16.11.2021

ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

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; KECI - 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; TECL - 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.

AU / EN