

**Fenbendazole (0.5%) Pellets Formulation**

Version 1.7      Revision Date: 30.09.2023      SDS Number: 7987908-00008      Date of last issue: 04.04.2023  
Date of first issue: 22.03.2021

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Fenbendazole (0.5%) Pellets Formulation

**Manufacturer or supplier's details**

Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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**2. HAZARDS IDENTIFICATION****GHS Classification**

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.  
**Response:**  
P391 Collect spillage.

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**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.

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 1 -< 10
fenbendazole	43210-67-9	>= 0.25 -< 1

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**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 : 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.

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

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**5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam

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		Carbon dioxide (CO <sub>2</sub> ) 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 Silicon 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.
Special protective equipment for firefighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### 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. 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.

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### 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 breathe dust.

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Do not swallow.  
 Avoid contact with eyes.  
 Avoid prolonged or repeated contact with skin.  
 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.  
 Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.  
 Store in accordance with the particular national regulations.  
 Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	PEL (long term) (Mist)	5 mg/m <sup>3</sup>	SG OEL
		PEL (short term) (Mist)	10 mg/m <sup>3</sup>	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
fenbendazole	43210-67-9	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### 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 : Combined particulates and organic vapour type  
 Hand protection :  
 Material : Chemical-resistant gloves  
 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.

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<p>Skin and body protection</p> <p>Hygiene measures</p>	<p>: Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</p> <p>: Work uniform or laboratory coat.</p> <p>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p>
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: pellets
Colour	: tan
	to
	light brown
Odour	: characteristic
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	: Not applicable
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

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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	:	No data available
Auto-ignition temperature	:	No data available
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

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**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.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

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**Components:****White mineral oil (petroleum):**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**fenbendazole:**

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg  
LD50 (Mouse): > 10,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Species : Rabbit  
Result : No skin irritation

**fenbendazole:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Species : Rabbit  
Result : No eye irritation

**fenbendazole:**

Species : Rabbit  
Result : No eye irritation

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**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Genotoxicity in vitro : 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: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**fenbendazole:**

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

Test Type: DNA Repair  
Result: negative

Test Type: Chromosomal aberration  
Result: negative

Test Type: in vitro assay  
Test system: mouse lymphoma cells  
Metabolic activation: Metabolic activation  
Result: equivocal

**Carcinogenicity**

Not classified based on available information.



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### Components:

#### **White mineral oil (petroleum):**

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	24 Months
Result	:	negative

#### **fenbendazole:**

Species	:	Mouse
Application Route	:	oral (feed)
Exposure time	:	2 Years
NOAEL	:	405 mg/kg body weight
Result	:	negative

Species	:	Rat
Application Route	:	Oral
Exposure time	:	2 Years
NOAEL	:	5 mg/kg body weight
Result	:	negative
Target Organs	:	Lymph nodes, Liver

### **Reproductive toxicity**

Not classified based on available information.

### Components:

#### **White mineral oil (petroleum):**

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative
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Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative
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#### **fenbendazole:**

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: oral (feed) General Toxicity - Parent: NOAEL: 15 mg/kg body weight Fertility: LOAEL: 45 mg/kg body weight Result: Effects on fertility
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Effects on foetal development	:	Test Type: Development Species: Dog, female Application Route: Oral Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-
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spring were detected., No teratogenic effects

Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 25 mg/kg body weight  
 Result: Fetotoxicity

Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 63 mg/kg body weight

Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 120 mg/kg body weight  
 Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### fenbendazole:

Exposure routes : Ingestion  
 Target Organs : Liver, Stomach, Nervous system, Lymph nodes  
 Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### White mineral oil (petroleum):

Species : Rat  
 LOAEL : 160 mg/kg  
 Application Route : Ingestion  
 Exposure time : 90 Days

Species : Rat  
 LOAEL :  $\geq 1$  mg/l  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 4 Weeks

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Method : OECD Test Guideline 412

**fenbendazole:**

Species : Rat  
LOAEL : 500 mg/kg  
Application Route : Oral  
Exposure time : 2 Weeks  
Target Organs : Kidney, Liver

Species : Rat  
NOAEL : > 2,500 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Remarks : No significant adverse effects were reported

Species : Rat  
LOAEL : 1,600 mg/kg  
Application Route : Oral  
Exposure time : 90 Days  
Target Organs : Central nervous system  
Symptoms : Tremors

Species : Dog  
NOAEL : 4 mg/kg  
LOAEL : 8 mg/kg  
Exposure time : 6 Months  
Target Organs : Stomach, Nervous system, Lymph nodes

**Aspiration toxicity**

Not classified based on available information.

**Components:****fenbendazole:**

No aspiration toxicity classification

**Experience with human exposure****Components:****fenbendazole:**

Ingestion : Symptoms: Rapid respiration, Salivation, anorexia, Diarrhoea

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****White mineral oil (petroleum):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

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Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l  
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
Exposure time: 21 d

### **fenbendazole:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.009 mg/l  
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.0088 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity) : 100

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.00113 mg/l  
Exposure time: 21 Days  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

### **Persistence and degradability**

#### **Components:**

#### **White mineral oil (petroleum):**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d

### **Bioaccumulative potential**

#### **Components:**

#### **fenbendazole:**

Partition coefficient: n-octanol/water : log Pow: 3.32

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**Mobility in soil****Components:****fenbendazole:**

Distribution among environmental compartments : log Koc: 3.8 - 4.7  
Method: FDA 3.08

**Other adverse effects**

No data available

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**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.

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

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(fenbendazole)  
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.  
(fenbendazole)  
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.  
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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.

**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.

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**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.**

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations	:	Not applicable
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Fire Safety (Petroleum and Flammable Materials) Regulations	:	Not applicable
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**The components of this product are reported in the following inventories:**

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

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**16. OTHER INFORMATION**

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**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 Agen- cy, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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Date format	:	dd.mm.yyyy
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**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
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SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average  
 SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term  
 SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

AIIIC - 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; 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.

SG / EN