

**Ivermectin (3.5%) Formulation**

Version 4.2      Revision Date: 30.09.2023      SDS Number: 4698080-00017      Date of last issue: 04.04.2023  
Date of first issue: 29.07.2019

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Ivermectin (3.5%) Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 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

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

Acute toxicity (Oral) : Category 4  
Specific target organ toxicity - single exposure (Oral) : Category 1 (Central nervous system)  
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)

**GHS label elements**

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.  
H370 Causes damage to organs (Central nervous system) if swallowed.  
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P260 Do not breathe vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.  
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

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**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ivermectin	70288-86-7	>= 1 -< 5
Aluminum tristearate	637-12-7	>= 1 -< 5

**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 if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
 Get medical attention if symptoms occur.
- 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 unless directed to do so by medical personnel.  
 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 : Harmful if swallowed.  
 Causes damage to organs if swallowed.  
 Causes 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.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing : None known.

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Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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**SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

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**SECTION 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 breathe vapors.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety

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- 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.
- 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.  
 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 labeled 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  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ivermectin	70288-86-7	TWA	30 µg/m <sup>3</sup> (OEB 3)	Internal
		Further information: Skin		
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal
Aluminum tristearate	637-12-7	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		VLE-PPT (Respirable fraction)	1 mg/m <sup>3</sup> (Aluminum)	NOM-010-STPS-2014
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

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**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 : Combined particulates and organic vapor 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.

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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : gel

Color : off-white

Odor : characteristic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : 170 °C

Flash point : 237.2 °C

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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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	0.93 - 0.95
Density	:	No data available
Solubility(ies) Water solubility	:	practically insoluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	382 - 384 mPa.s ( 25 °C)
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

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**SECTION 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.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,511 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

**Components:****Ivermectin:**

Acute oral toxicity : LD50 (Rat): 50 mg/kg  
LD50 (Mouse): 25 mg/kg  
LD50 (Monkey): > 24 mg/kg  
Target Organs: Central nervous system  
Symptoms: Vomiting, Dilatation of the pupil  
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l  
Exposure time: 1 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg  
LD50 (Rat): > 660 mg/kg

**Aluminum tristearate:**

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

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**Components:****Ivermectin:**

Species : Rabbit  
Result : No skin irritation

**Aluminum tristearate:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : Based on data from similar materials  
  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Ivermectin:**

Species : Rabbit  
Result : Mild eye irritation

**Aluminum tristearate:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Ivermectin:**

Routes of exposure : Dermal  
Species : Humans  
Result : Does not cause skin sensitization.

**Aluminum tristearate:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials



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**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Ivermectin:**

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: human diploid fibroblasts  
Result: negative

Test Type: Mouse Lymphoma  
Result: negative

**Aluminum tristearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:****Ivermectin:**

Species : Rat  
Application Route : Oral  
NOAEL : 1.5 mg/kg body weight  
Result : negative  
Remarks : Based on data from similar materials

Species : Mouse  
Application Route : Oral  
NOAEL : 2.0 mg/kg body weight  
Result : negative  
Remarks : Based on data from similar materials

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**Reproductive toxicity**

Not classified based on available information.

**Components:****Ivermectin:**

- Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 0.6 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.
- Effects on fetal development : Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 0.2 mg/kg body weight  
Result: Teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
- Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.4 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected.  
Remarks: The mechanism or mode of action may not be relevant in humans.
- Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Result: Teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

**Aluminum tristearate:**

- Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials
- Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**STOT-single exposure**

Causes damage to organs (Central nervous system) if swallowed.

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**Components:****Ivermectin:**

Target Organs : Central nervous system  
Assessment : Causes damage to organs.

**STOT-repeated exposure**

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

**Components:****Ivermectin:**

Target Organs : Central nervous system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Ivermectin:**

Species : Dog  
NOAEL : 0.5 mg/kg  
LOAEL : 1 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Target Organs : Central nervous system  
Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species : Monkey  
NOAEL : 1.2 mg/kg  
Application Route : Oral  
Exposure time : 2 Weeks  
Remarks : No significant adverse effects were reported

Species : Rat  
NOAEL : 0.4 mg/kg  
LOAEL : 0.8 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : spleen, Bone marrow, Kidney

**Aluminum tristearate:**

Species : Rat  
NOAEL :  $\geq 5,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

**Aspiration toxicity**

Not classified based on available information.

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**Experience with human exposure****Components:****Ivermectin:**

Skin contact : Remarks: Can be absorbed through skin.  
Eye contact : Remarks: May irritate eyes.  
Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Ivermectin:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l  
Exposure time: 96 h  
  
LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l  
Exposure time: 96 h  
  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.000025 mg/l  
Exposure time: 48 h  
  
Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
  
NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

**Aluminum tristearate:****Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded  
Chronic aquatic toxicity : Toxic effects cannot be excluded

**Persistence and degradability****Components:****Ivermectin:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 240 d

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**Bioaccumulative potential****Components:****Ivermectin:**

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-octanol/water : log Pow: 3.22

**Mobility in soil**

No data available

**Other adverse effects**No data available

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**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.

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

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

**IATA-DGR**

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
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. (Ivermectin)

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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.

**Domestic regulation****NOM-002-SCT**

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
Class	:	9
Packing group	:	III
Labels	:	9

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

**The ingredients of this product are reported in the following inventories:**

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

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**SECTION 16. OTHER INFORMATION**

Revision Date	:	30.09.2023
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**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value

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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; 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

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8