SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Pyrantel Pamoate / Ivermectin Formulation

Version 1.2  Revision Date: 2020/05/20  SDS Number: 4892866-00003  Date of last issue: 2020/03/23

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Pyrantel Pamoate / Ivermectin Formulation

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>paste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

May be harmful if swallowed. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification
Acute toxicity (Oral): Category 5
Specific target organ toxicity - single exposure: Category 2
Specific target organ toxicity - repeated exposure: Category 2
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: 

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**Signal word:** Warning

**Hazard statements:**
- H303 May be harmful if swallowed.
- H371 May cause damage to organs.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

**Precautionary statements:**

**Prevention:**
- P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.

**Response:**
- P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
- P391 Collect spillage.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents/ container to an approved waste disposal plant.

**Physical and chemical hazards**
Not classified based on available information.

**Health hazards**
May be harmful if swallowed. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure.

**Environmental hazards**
Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

**Additional Labelling**
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 38.3 %

**Other hazards which do not result in classification**
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,4’-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)</td>
<td>22204-24-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>
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:
May be harmful if swallowed.
May cause damage to organs.
May cause damage to organs through prolonged or repeated exposure.

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 (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
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.

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 and personal protective equipment.
Emergency procedures

Environmental precautions: Discharge into the environment must be avoided. 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: 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

Handling

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: 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. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Storage

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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>
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: Combined particulates and organic vapour type

Eye/face 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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES
### Pyrantel Pamoate / Ivermectin Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>paste</td>
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<td>Colour</td>
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<td>Odour</td>
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<td>Odour Threshold</td>
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<td>pH</td>
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<td>Initial boiling point and boiling range</td>
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<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
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<td>Flammability (liquids)</td>
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<td>Vapour pressure</td>
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<td>Density</td>
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<td>Solubility(ies)</td>
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<td></td>
<td>No data available</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
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<td>Auto-ignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Viscosity</td>
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<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
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<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
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

Exposure routes: Skin contact
Ingestion
Eye contact

Acute toxicity
May be harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 3,334 mg/kg
Method: Calculation method

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

Components:
4,4′-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-
methy1-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Acute oral toxicity: LD50 (Rat): > 24,000 mg/kg
LD50 (Mouse): > 24,000 mg/kg
LD50 (Dog): 2,000 mg/kg

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

Skin corrosion/irritation
Not classified based on available information.

**Components:**

**Ivermectin:**
- Species: Rabbit
- Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

**Components:**

**Ivermectin:**
- Species: Rabbit
- Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

**Components:**

**Ivermectin:**
- Exposure routes: Dermal
- Species: Humans
- Result: Does not cause skin sensitisation.

Germ cell mutagenicity
Not classified based on available information.

**Components:**

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES); Result: negative

**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

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

Reproductive toxicity
Not classified based on available information.

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

**Ivermectin:**

Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 0.6 mg/kg body weight
Effects on foetal 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

**STOT - single exposure**
May cause damage to organs.

**Components:**

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

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.

**Components:**

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

**Repeated dose toxicity**

**Components:**

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

- **Species:** Dog
- **NOAEL:** 10 mg/kg
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Date of first issue: 2019/09/17

LOAEL: 30 mg/kg  
Application Route: Ingestion  
Exposure time: 3 d  
Remarks: No significant adverse effects were reported

Species: Dog  
NOAEL: 600 mg/kg  
Application Route: Oral  
Exposure time: 19 d  
Remarks: No significant adverse effects were reported

Species: Dog  
NOAEL: 600 mg/kg  
Application Route: Oral  
Exposure time: 30 d  
Remarks: No significant adverse effects were reported

Species: Dog  
NOAEL: 600 mg/kg  
Application Route: Oral  
Exposure time: 90 d  
Remarks: No significant adverse effects were reported

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
4,4’-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienylvinyl)pyrimidine (1:1):
## Ingestion

### Symptoms:
- Abdominal pain
- Nausea
- Vomiting
- Diarrhoea
- Headache
- Dizziness
- Fever

### 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

## ECOLOGICAL INFORMATION

### Ecotoxicity
#### Components:
- 4,4’-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

#### Ecotoxicology Assessment
- Acute aquatic toxicity: Toxic effects cannot be excluded
- Chronic aquatic toxicity: Toxic effects cannot be excluded

### 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

- M-Factor (Acute aquatic toxicity): 10,000
- M-Factor (Chronic aquatic toxicity): 10,000

### Persistence and degradability
#### Components:
- Ivermectin:
  - Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 240 d

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

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Ivermectin)
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. (Ivermectin)
Class : 9
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
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

GB 6944/12268
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, 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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

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

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd
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Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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; 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

Disclaimer
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.

CN / EN