

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Enrofloxacin Liquid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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 in accordance with ABNT NBR 14725 Standard**

Skin irritation : Category 2

Eye irritation : Category 2A

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 2 (cartilage, Testis)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H315 Causes skin irritation.

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## Enrofloxacin Liquid Formulation

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
 Date of first issue: 12.11.2021

H319 Causes serious eye irritation.  
 H361f Suspected of damaging fertility.  
 H373 May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.  
 H410 Very toxic to aquatic life with long lasting effects.

## Precautionary Statements

: **Prevention:**  
 P201 Obtain special instructions before use.  
 P264 Wash skin thoroughly after handling.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P391 Collect spillage.

**Other hazards which do not result in classification**

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.    | Classification   | Concentration (% w/w) |
|---------------------|------------|--|-----------------------|
| Enrofloxacin        | 93106-60-6 | Acute toxicity (Oral), Category 4<br>Acute toxicity (Dermal), Category 5<br>Reproductive toxicity, Category 2<br>Specific target organ toxicity - repeated exposure (cartilage, Testis), Category 1<br>Short-term (acute) aquatic hazard, Category 1<br>Long-term (chronic) aquatic hazard, Category 1 | >= 5 -< 10            |
| Potassium hydroxide | 1310-58-3  | Corrosive to Metals, Category 1<br>Acute toxicity (Oral), Category 4<br>Skin corrosion, Category 1A<br>Serious eye damage, Category 1  | >= 1 -< 2             |

## Enrofloxacin Liquid Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 01.10.2022  |
| 1.4     | 04.04.2023     | 10223969-00005 | Date of first issue: 12.11.2021 |

### SECTION 4. FIRST AID MEASURES

- |   |   |  |
|---|---|--|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.   |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.   |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : | Causes skin irritation.<br>Causes serious eye irritation.<br>Suspected of damaging fertility.<br>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.  |

### SECTION 5. FIRE-FIGHTING MEASURES

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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<br>Metal oxides   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

## Enrofloxacin Liquid Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 01.10.2022  |
| 1.4     | 04.04.2023     | 10223969-00005 | Date of first issue: 12.11.2021 |

---

- 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.  
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.  
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.  
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 : 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 mist or vapors.  
Do not swallow.  
Do not get in 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

## Enrofloxacin Liquid Formulation

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
 Date of first issue: 12.11.2021

- 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    |
|---------------------|------------|-------------------------------|--|----------|
| Enrofloxacin        | 93106-60-6 | TWA                           | 0.2 mg/m <sup>3</sup> (OEB 2)                  | Internal |
| Potassium hydroxide | 1310-58-3  | C                             | 2 mg/m <sup>3</sup>                            | ACGIH    |

- 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.  
 Laboratory operations do not require special containment.

**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 : Chemical-resistant gloves
- Material
- 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.

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|  |   |   |
|--|---|---|
| Appearance                                       | : | Aqueous solution  |
| Color  | : | Clear white to yellow.  |
| Odor   | : | No data available   |
| Odor Threshold                                   | : | No data available   |
| pH   | : | 10,5 - 12,5   |
| 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   |
| Vapor pressure                                   | : | No data available   |
| Relative vapor density                           | : | No data available   |
| Relative density                                 | : | No data available   |
| Density  | : | No data available   |
| Solubility(ies)<br>Water solubility              | : | No data available   |
| Partition coefficient: n-octanol/water           | : | Not applicable  |
| Autoignition temperature                         | : | No data available   |
| Decomposition temperature                        | : | No data available   |
| Viscosity<br>Viscosity, kinematic                | : | No data available   |
| Explosive properties                             | : | Not explosive   |

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

---

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 : 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  
Acids  
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**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg  
Method: Calculation method

**Components:****Enrofloxacin:**

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg  
LD50 (Rat): > 5.000 mg/kg  
LD50 (Mouse): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

**Potassium hydroxide:**

Acute oral toxicity : LD50 (Rat): 333 mg/kg

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

---

**Skin corrosion/irritation**

Causes skin irritation.

**Components:****Enrofloxacin:**

Result : No skin irritation

**Potassium hydroxide:**

Species : Rabbit

Result : Corrosive after 3 minutes or less of exposure

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Enrofloxacin:**

Result : Mild eye irritation

**Potassium hydroxide:**

Species : Rabbit

Result : Irreversible effects on the eye

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

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Enrofloxacin:**

Test Type : Maximization Test

Routes of exposure : Dermal

Species : Guinea pig

Result : Not a skin sensitizer.

**Potassium hydroxide:**

Test Type : Intracutaneous test

Routes of exposure : Skin contact

Species : Guinea pig

Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Enrofloxacin:**



## Enrofloxacin Liquid Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 01.10.2022  |
| 1.4     | 04.04.2023     | 10223969-00005 | Date of first issue: 12.11.2021 |

---

Genotoxicity in vitro : Test Type: Chromosomal aberration  
Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

Test Type: Mammalian bone marrow sister chromatid exchange  
Species: Hamster  
Result: negative

Test Type: Chromosomal aberration  
Species: Rat  
Result: negative

### Potassium hydroxide:

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### Enrofloxacin:

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

### Reproductive toxicity

Suspected of damaging fertility.

### Components:

#### Enrofloxacin:

Effects on fertility : Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 15 mg/kg body weight  
Result: Effects on fertility., alteration in sperm morphology

Effects on fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 210 mg/kg body weight  
Result: Reduced fetal weight., No teratogenic effects.  
Remarks: Maternal toxicity observed.

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

---

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 25 mg/kg body weight  
Result: No fetotoxicity., No teratogenic effects.

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

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.

**Components:****Enrofloxacin:**

Target Organs : cartilage, Testis  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Enrofloxacin:**

Species : Rat  
NOAEL : 36 mg/kg  
LOAEL : 150 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks  
Target Organs : Testis

Species : Dog  
NOAEL : 3 mg/kg  
LOAEL : 9,6 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks  
Target Organs : cartilage

Species : Cat  
NOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Remarks : No significant adverse effects were reported

**Aspiration toxicity**

Not classified based on available information.

## Enrofloxacin Liquid Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 01.10.2022  |
| 1.4     | 04.04.2023     | 10223969-00005 | Date of first issue: 12.11.2021 |

### Experience with human exposure

#### Components:

#### Enrofloxacin:

Ingestion : Symptoms: Gastrointestinal disturbance, central nervous system effects, Sensitivity to light

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Enrofloxacin:

|  |   |   |
|--|---|---|
| Toxicity to fish   | : | LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): 79,5 mg/l<br>Exposure time: 96 h       |
|  |   | LC50 ( <i>Oncorhynchus mykiss</i> (rainbow trout)): > 196 mg/l<br>Exposure time: 96 h         |
|  |   | LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l<br>Exposure time: 96 h           |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 ( <i>Hyalella azteca</i> (Amphipod)): > 206 mg/l<br>Exposure time: 96 h                  |
|  |   | EC50 ( <i>Daphnia magna</i> (Water flea)): 79,9 mg/l<br>Exposure time: 48 h                   |
| Toxicity to algae/aquatic plants                                       | : | EC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 3,1 mg/l<br>Exposure time: 72 h |
|  |   | EC50 ( <i>Microcystis aeruginosa</i> (blue-green algae)): 0,049 mg/l<br>Exposure time: 5 d    |
| M-Factor (Acute aquatic toxicity)                                      | : | 10  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC ( <i>Daphnia magna</i> (Water flea)): 9,8 mg/l<br>Exposure time: 21 d                    |
|  |   | NOEC ( <i>Daphnia magna</i> (Water flea)): 5 mg/l<br>Exposure time: 21 d                      |
|  |   | LOEC ( <i>Daphnia magna</i> (Water flea)): 15 mg/l<br>Exposure time: 21 d                     |
| M-Factor (Chronic aquatic toxicity)                                    | : | 10  |

#### **Persistence and degradability**

No data available

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

---

**Bioaccumulative potential****Components:****Enrofloxacin:**

Partition coefficient: n-octanol/water : log Pow: 0,5

**Mobility in soil****Components:****Enrofloxacin:**

Distribution among environmental compartments : Koc: 5,55

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.  
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.  
(Enrofloxacin)  
Class : 9  
Packing group : III  
Labels : 9

**IATA-DGR**

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

**IMDG-Code**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

**Enrofloxacin Liquid Formulation**

Version 1.4      Revision Date: 04.04.2023      SDS Number: 10223969-00005      Date of last issue: 01.10.2022  
Date of first issue: 12.11.2021

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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****ANTT**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(Enrofloxacin)  
Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

**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**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Potassium hydroxide

**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 : 04.04.2023  
Date format : dd.mm.yyyy

**Further information**

**Enrofloxacin Liquid Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 01.10.2022  |
| 1.4     | 04.04.2023     | 10223969-00005 | Date of first issue: 12.11.2021 |

---

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/>

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / C : Ceiling limit

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.

BR / Z8