

**Enrofloxacin (2.5%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	28.09.2024	641542-00020	Date of first issue: 27.04.2016

**SECTION 1. IDENTIFICATION**

Product name : Enrofloxacin (2.5%) Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

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

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

Skin sensitization : Category 1

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**

Hazard pictograms



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.  
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:**

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P260 Do not breathe mist or vapors.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P314 Get medical advice/ attention if you feel unwell.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
P391 Collect spillage.

**Disposal:**

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

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

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Enrofloxacin	93106-60-6	$\geq 2,5$ -< 3
Benzyl alcohol	100-51-6	$\geq 1$ -< 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.

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 : Flush eyes with water as a precaution.  
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 : May cause an allergic skin reaction.  
May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

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Notes to physician : and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  
: 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 media : None known.

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

Hazardous combustion products : Carbon 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.

**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

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employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

- |                             |   |  |
|-----------------------------|---|--|
| Technical measures          | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation     | : | Use only with adequate ventilation.  |
| Advice on safe handling     | : | Do not get on skin or clothing.<br>Do not breathe mist or vapors.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>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

- |                             |   |   |
|-----------------------------|---|---|
| <b>Engineering measures</b> | : | Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).<br>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.<br>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            | : | Combined particulates and organic vapor type   |

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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. 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.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: liquid
Color	: No data available
Odor	: No data available
Odor 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	: No data available
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

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Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics	:	
Particle size	:	Not applicable

**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.

**SECTION 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.

**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

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**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

**Benzyl alcohol:**

Acute oral toxicity	:	LD50 (Rat): 1.200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5,4 mg/l
		Exposure time: 4 h
		Test atmosphere: dust/mist
		Method: OECD Test Guideline 403
		Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**

|| Not classified based on available information.

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

Result	:	No skin irritation
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**Benzyl alcohol:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

**Serious eye damage/eye irritation**

|| Not classified based on available information.

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

Result	:	Mild eye irritation
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**Benzyl alcohol:**

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

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

|| May cause an allergic skin reaction.

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**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.

**Benzyl alcohol:**

Test Type	: Human repeat insult patch test (HRIPT)
Routes of exposure	: Skin contact
Species	: Humans
Result	: positive

Assessment	: Probability or evidence of low to moderate skin sensitization rate in humans
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**Germ cell mutagenicity**

|| Not classified based on available information.

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

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

**Benzyl alcohol:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

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**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

**Benzyl alcohol:**

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

**Reproductive toxicity**

|| Not classified based on available information.

**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
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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.
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	:	Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 25 mg/kg body weight Result: No fetotoxicity., No teratogenic effects.
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Reproductive toxicity - Assessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
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**Benzyl alcohol:**

Effects on fertility	:	Test Type: Fertility/early embryonic development
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Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**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

**Benzyl alcohol:**

Species : Rat  
NOAEL : 1,072 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

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**Aspiration toxicity**

|| Not classified based on available information.

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

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**Benzyl alcohol:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

**Persistence and degradability****Components:****Benzyl alcohol:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
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**Bioaccumulative potential****Components:****Enrofloxacin:**

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

Partition coefficient: n-octanol/water	:	log Pow: 1,05
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**Mobility in soil****Components:****Enrofloxacin:**

Distribution among environmental compartments	:	Koc: 5,55
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**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.

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024  
Date format : dd.mm.yyyy

**Further information**

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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of other abbreviations**

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

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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.

AR / Z8