

Enrofloxacin Liquid Formulation

Version 4.0 Revision Date: 06.07.2024 SDS Number: 10223967-00008 Date of last issue: 06.04.2024
Date of first issue: 12.11.2021

SECTION 1. IDENTIFICATION

Product name : Enrofloxacin Liquid 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 corrosion/irritation : Category 2

Serious eye damage/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

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H315 Causes skin irritation.

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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.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe mist or vapors.
 P264 Wash skin thoroughly after handling.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.
 P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

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. | Concentration (% w/w) |
|---------------------|------------|-----------------------|
| Enrofloxacin | 93106-60-6 | >= 5 -< 10 |
| Potassium hydroxide | 1310-58-3 | >= 1 -< 2 |
| Benzyl alcohol | 100-51-6 | >= 0,1 -< 1 |

SECTION 4. FIRST AID MEASURES

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- | | | |
|---|---|--|
| 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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. 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. If easy to do, remove contact lens, if worn. Get medical attention. |
| 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 | : | Causes skin irritation. Causes serious eye irritation. Suspected of damaging fertility. 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 Alcohol-resistant foam Carbon dioxide (CO ₂) 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 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. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
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| Personal precautions, protective equipment and emergency measures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal |
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Materials to avoid : Store in accordance with the particular national regulations.
 : 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 ³ (OEB 2) | Internal |
| Potassium hydroxide | 1310-58-3 | CMP-C | 2 mg/m ³ | AR OEL |
| | | C | 2 mg/m ³ | 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

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.
 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.

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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) 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 |

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Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
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 : 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.

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

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

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

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

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

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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.

Potassium hydroxide:

Test Type : Intracutaneous test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Benzyl alcohol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

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

Potassium hydroxide:

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

Benzyl alcohol:

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

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Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
 Species: Mouse
 Application Route: Intraperitoneal injection
 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

Benzyl alcohol:

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

Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: NOAEL: 25 mg/kg body weight

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Result: No fetotoxicity., No teratogenic effects.

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

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
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

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Benzyl alcohol:

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

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 (Lepomis macrochirus (Bluegill sunfish)): 79,5 mg/l Exposure time: 96 h |
| | : LC50 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l Exposure time: 96 h |
| | : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Hyaella azteca (Amphipod)): > 206 mg/l Exposure time: 96 h |
| | : EC50 (Daphnia magna (Water flea)): 79,9 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : EC50 (Pseudokirchneriella subcapitata (green algae)): 3,1 mg/l Exposure time: 72 h |
| | : EC50 (Microcystis aeruginosa (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 (Daphnia magna (Water flea)): 9,8 mg/l Exposure time: 21 d |
| | : NOEC (Daphnia magna (Water flea)): 5 mg/l |

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Exposure time: 21 d

LOEC (Daphnia magna (Water flea)): 15 mg/l
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 10

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

Bioaccumulative potential

Components:

Enrofloxacin:

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

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1,05

Mobility in soil

Components:

Enrofloxacin:

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Distribution among environmental compartments : Koc: 5,55

Other adverse effects

No data available

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.
(Enrofloxacin)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : no

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, N.O.S.
(Enrofloxacin)

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.

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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.

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 : 06.07.2024
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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / C : Ceiling limit
AR OEL / CMP-C : Ceiling value

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

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- 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.

AR / Z8