

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
Date of first issue: 12.11.2021

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Enrofloxacin Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
 Date of first issue: 12.11.2021

- Hazard pictograms : 
- Signal word : Warning
- Hazard statements : H315 Causes skin irritation.
 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:**
 P203 Obtain, read and follow all safety instructions before use.
 P260 Do not breathe mist or vapours.
 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.
 P318 IF exposed or concerned, get medical advice.
 P332 + P317 If skin irritation occurs: Get medical help.
 P337 + P317 If eye irritation persists: Get medical help.
 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.

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

4. FIRST AID MEASURES

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
 Date of first issue: 12.11.2021

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.

5. FIREFIGHTING 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protection	:	Use personal protective equipment.
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Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

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| tive equipment and emergency procedures | : | 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 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

- | | | |
|-----------------------------|---|--|
| 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 the mist or vapours.
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. |
| Conditions for safe storage | : | Keep in properly labelled containers.
Store locked up.
Store in accordance with the particular national regulations. |

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
Date of first issue: 12.11.2021

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : Clear white to yellow.

Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

Odour	:	No data available
Odour 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
Vapour pressure	:	No data available
Relative vapour 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
Auto-ignition 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.
Molecular weight	:	No data available
Particle size	:	Not applicable

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
Date of first issue: 12.11.2021

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.

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
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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.

Skin corrosion/irritation

Causes skin irritation.

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
Date of first issue: 12.11.2021

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 sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Enrofloxacin:**

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

Potassium hydroxide:

Test Type : Intracutaneous test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**Enrofloxacin:**

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

Enrofloxacin Liquid Formulation

Version 1.4 Revision Date: 04.04.2023 SDS Number: 10223975-00005 Date of last issue: 01.10.2022
Date of first issue: 12.11.2021

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

Test Type: Development
Species: Rabbit

Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

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.

Experience with human exposure

Components:

Enrofloxacin:

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

Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Enrofloxacin:

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| 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 (Hyalella 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: 9.8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

NOEC: 5 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

LOEC: 15 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea) |
| M-Factor (Chronic aquatic toxicity) | : | 10 |

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Enrofloxacin:

Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

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

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.

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, N.O.S.
(Enrofloxacin)
Class : 9

Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to IMO instruments

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.

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

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

16. OTHER INFORMATION

Revision Date	:	04.04.2023
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Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
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Date format	:	dd.mm.yyyy
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Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
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ACGIH / C	:	Ceiling limit
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All - 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

Enrofloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
1.4	04.04.2023	10223975-00005	Date of first issue: 12.11.2021

Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN