

SAFETY DATA SHEET



Enrofloxacin Liquid (20%) Formulation

Version
9.0

Revision Date:
2025/04/14

SDS Number:
9743088-00012

Date of last issue: 2024/09/28
Date of first issue: 2021/10/13

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Enrofloxacin Liquid (20%) Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Acute toxicity (Oral) : Category 4

Skin corrosion/irritation : Sub-category 1A

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 1 (cartilage, Testis)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

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| Hazard statements | : H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H361f Suspected of damaging fertility. H372 Causes 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 vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor. P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor. P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor. P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P363 Wash contaminated clothing 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 | |
| Important symptoms and outlines of the emergency assumed | : Corrosive to the respiratory tract. May form explosive dust-air mixture during processing, handling or other means. |

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|--------------------------|------------|-----------------------|----------------|
| Enrofloxacin | 93106-60-6 | >= 20 - < 25 | - |
| Potassium hydroxide | 1310-58-3 | >= 2.5 - <= 5 | 1-369 |
| Disodium EDTA, dihydrate | 6381-92-6 | 1 | 2-1265, 2-1265 |
| Benzyl alcohol | 100-51-6 | >= 0.1 - < 1 | 3-1011 |

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.

If not breathing, give artificial respiration.

If breathing is difficult, give oxygen.

Get medical attention immediately.

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 immediately.

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 immediately.

If swallowed

: If swallowed, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

: Causes digestive tract burns.

Corrosive to respiratory system.

Harmful if swallowed.

Causes serious eye damage.

Suspected of damaging fertility.

Causes damage to organs through prolonged or repeated exposure.

Causes severe burns.

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

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|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 Nitrogen oxides (NO _x) |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for firefighters | : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| | |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment. Follow safe handling advice (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 dis- |

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posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE**Handling**

Technical measures

- : 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

- : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling

- : Do not get on skin or clothing.
- Do not breathe 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
- Keep container tightly closed.
- 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.

Avoidance of contact

- : Oxidizing agents
- Acids

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.

Storage

Conditions for safe storage

- : Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid

- : Do not store with the following product types:
- Strong oxidizing agents

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Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Concentration standard / Permissible concentration | Basis |
|---------------------|---------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------------------------------------------|-------------|
| Enrofloxacin | 93106-60-6 | TWA | 0.2 mg/m3 (OEB 2) | Internal |
| Potassium hydroxide | 1310-58-3 | OEL-C | 2 mg/m3 | JP OEL JSOH |
| | | C | 2 mg/m3 | ACGIH |
| Benzyl alcohol | 100-51-6 | OEL-C | 25 mg/m3 | JP OEL JSOH |
| | Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans. | | | |

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

Remarks : Impermeable protective 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Aqueous solution

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Colour : light yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : 10.5 - 12.5

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : 0.950 - 1.150 g/cm³

Relative vapour density : No data available

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| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

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

Harmful if swallowed.

Product:

| | | |
|---------------------------|---|---------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: 1,818 mg/kg Method: Calculation method |
| Acute inhalation toxicity | : | Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method |

Components:

Enrofloxacin:

| | | |
|---------------------|---|-------------------------------------------------------------|
| Acute oral toxicity | : | LD50 (Rabbit): 500 - 800 mg/kg LD50 (Rat): > 5,000 mg/kg |
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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.

Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 1 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 412

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

Causes severe burns.

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 damage.

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Components:

Enrofloxacin:

|||Result : Mild eye irritation

Potassium hydroxide:

||Species : Rabbit
||Result : Irreversible effects on the eye

Disodium EDTA, dihydrate:

||Species : Rabbit
||Result : No eye irritation

Benzyl alcohol:

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

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

Disodium EDTA, dihydrate:

||Test Type : Maximisation Test
||Exposure routes : Skin contact
||Species : Guinea pig
||Method : OECD Test Guideline 406
||Result : negative
||Remarks : Based on data from similar materials

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Benzyl alcohol:

| | | |
|-----------------|---|------------------------------------------------------------------------------|
| Test Type | : | Human repeat insult patch test (HRIPT) |
| Exposure routes | : | Skin contact |
| Species | : | Humans |
| Result | : | positive |
| Assessment | : | Probability or evidence of low to moderate skin sensitisation rate in humans |

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 |
|-----------------------|---|------------------------------------------------------------------------|

Disodium EDTA, dihydrate:

| | | |
|-----------------------|---|-------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials |
| | : | Test Type: In vitro mammalian cell gene mutation test Result: negative |
| | : | Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse |

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Application Route: Ingestion
Method: OECD Test Guideline 474
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 |

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 |

Disodium EDTA, dihydrate:

| | |
|-------------------|----------------------------------------|
| Species | : Rat |
| Application Route | : Ingestion |
| Exposure time | : 103 weeks |
| Result | : negative |
| Remarks | : Based on data from similar materials |

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:

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|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 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. |
| Disodium EDTA, dihydrate: | |
| Effects on fertility | : Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative |
| 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 foetal development | : Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative |
| STOT - single exposure | |
| Not classified based on available information. | |

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STOT - repeated exposure

Causes 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. |

Disodium EDTA, dihydrate:

| | | |
|-----------------|---|--------------------------------------------------------------------|
| Exposure routes | : | inhalation (dust/mist/fume) |
| Target Organs | : | Respiratory Tract |
| Assessment | : | May cause 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 |

Disodium EDTA, dihydrate:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| NOAEL | : | 500 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 13 Weeks |

| | | |
|-------------------|---|-----------------------------|
| Species | : | Rat |
| LOAEL | : | 0.03 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 4 Weeks |

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Method : OECD Test Guideline 412

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 |
|-----------|------------------------------------------------------------------------------------------------|

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 tox-) | : 10 |

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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
Exposure time: 21 d

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

M-Factor (Chronic aquatic toxicity): 10

Disodium EDTA, dihydrate:

Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 140 mg/l
Exposure time: 48 h
Method: DIN 38412

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 25 mg/l
Exposure time: 21 d

Toxicity to microorganisms: EC10 (activated sludge): > 500 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

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

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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:

Disodium EDTA, dihydrate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 2 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

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

Disodium EDTA, dihydrate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: -4.3

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Mobility in soil

Components:

Enrofloxacin:

Distribution among environ- : Koc: 5.55

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Environmental compartments

Hazardous to the ozone layer

Not applicable

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 1814
Proper shipping name : POTASSIUM HYDROXIDE SOLUTION
Class : 8
Packing group : II
Labels : 8
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1814
Proper shipping name : Potassium hydroxide solution
Class : 8
Packing group : II
Labels : Corrosive
Packing instruction (cargo aircraft) : 855
Packing instruction (passenger aircraft) : 851

IMDG-Code

UN number : UN 1814
Proper shipping name : POTASSIUM HYDROXIDE SOLUTION (Enrofloxacin)
Class : 8
Packing group : II
Labels : 8
EmS Code : F-A, S-B
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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National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 154

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

| Chemical name | Number |
|--------------------------------------------------------------------------|--------|
| Sodium salt of 2,2',2'',2'''-(ethane-1,2-diyl)dinitrilo)tetraacetic acid | 268 |

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

| Chemical name | Concentration (%) | Remarks |
|---------------------|-------------------|---------|
| Potassium hydroxide | >=2.5 - <=5 | - |

Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

| Chemical name | Remarks |
|---------------------|---------|
| Potassium hydroxide | - |

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Chemical name

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Potassium hydroxide

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

| Chemical name | Administration number | Concentration (%) |
|--------------------------------------------------------------------|-----------------------|-------------------|
| Ethylenediaminetetraacetic acid and its potassium and sodium salts | 595 | 1.0 |

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Corrosive substances (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Corrosive substances (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

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Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

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

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / C : Ceiling limit
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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;

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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.

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