

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Enrofloxacin Liquid (20%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

| | |
|--|---|
| Acute toxicity, Category 4 | H302: Harmful if swallowed. |
| Skin corrosion, Sub-category 1A | H314: Causes severe skin burns and eye damage. |
| Serious eye damage, Category 1 | H318: Causes serious eye damage. |
| Reproductive toxicity, Category 2 | H361f: Suspected of damaging fertility. |
| Specific target organ toxicity - repeated exposure, Category 1 | H372: Causes damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects. |

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

| | | |
|--------------------------------|---|--|
| Hazard pictograms | : | |
| Signal word | : | Danger |
| Hazard statements | : | H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H361f Suspected of damaging fertility. H372 Causes damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects. |
| Supplemental Hazard Statements | : | EUH071 Corrosive to the respiratory tract. |
| Precautionary statements | : | Prevention: P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: 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. 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. P391 Collect spillage. |

Hazardous components which must be listed on the label:

Enrofloxacin
Potassium hydroxide

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

May form explosive dust-air mixture during processing, handling or other means.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|--------------------------|---|--|--------------------------|
| Enrofloxacin | 93106-60-6 | Acute Tox. 4; H302 Repr. 2; H361f STOT RE 1; H372 (cartilage, Testis) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10 | >= 20 - < 25 |
| Potassium hydroxide | 1310-58-3 215-181-3 019-002-00-8 | Met. Corr. 1; H290 Acute Tox. 4; H302 Skin Corr. 1A; H314 Eye Dam. 1; H318 EUH014, EUH071 specific concentra- tion limit Skin Corr. 1A; H314 >= 5 % Skin Corr. 1B; H314 2 - < 5 % Skin Irrit. 2; H315 0,5 - < 2 % Eye Irrit. 2; H319 0,5 - < 2 % EUH071 >= 2 % Acute toxicity esti- mate Acute oral toxicity: 333 mg/kg | >= 5 - < 10 |
| Disodium EDTA, dihydrate | 6381-92-6 | Acute Tox. 4; H332 | >= 1 - < 10 |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

| | | | |
|--|--|--|--|
| | | STOT RE 2; H373 (Respiratory Tract) | |
|--|--|--|--|

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Harmful if swallowed.
Causes serious eye damage.
Suspected of damaging fertility.
Causes damage to organs through prolonged or repeated exposure.
Causes severe burns.
Corrosive to the respiratory tract.
- Causes digestive tract burns.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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)

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

SAFETY DATA SHEET

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Enrofloxacin Liquid (20%) Formulation

| | | | |
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| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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 contami-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



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Date of first issue: 13.10.2021

nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------|------------|-------------------------------|-------------------------------|---------------------|
| Enrofloxacin | 93106-60-6 | TWA | 0.2 mg/m ³ (OEB 2) | Internal |
| Potassium hydroxide | 1310-58-3 | T | 2 mg/m ³ | FOR-2011-12-06-1358 |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|--------------------------|-----------|-----------------|----------------------------|-----------------------|
| Potassium hydroxide | Workers | Inhalation | Long-term local effects | 1 mg/m ³ |
| | Consumers | Inhalation | Long-term local effects | 1 mg/m ³ |
| Disodium EDTA, dihydrate | Workers | Inhalation | Long-term systemic effects | 1,5 mg/m ³ |
| | Workers | Inhalation | Acute systemic effects | 3 mg/m ³ |
| | Workers | Inhalation | Long-term local effects | 1,5 mg/m ³ |
| | Workers | Inhalation | Acute local effects | 3 mg/m ³ |
| | Consumers | Inhalation | Long-term local effects | 0,6 mg/m ³ |
| | Consumers | Inhalation | Acute local effects | 1,2 mg/m ³ |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

| | | | | |
|--|-----------|-----------|----------------------------|-----------------|
| | Consumers | Ingestion | Long-term systemic effects | 25 mg/kg bw/day |
|--|-----------|-----------|----------------------------|-----------------|

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|--------------------------|---------------------------|-----------------------------|
| Disodium EDTA, dihydrate | Fresh water | 2,5 mg/l |
| | Marine water | 0,25 mg/l |
| | Sewage treatment plant | 50 mg/l |
| | Soil | 1,1 mg/kg dry weight (d.w.) |

8.2 Exposure controls

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

- Eye/face 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.
- Hand protection
Material : Chemical-resistant gloves
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to NS EN 143
- Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Physical state : Aqueous solution
- Colour : light yellow
- Odour : No data available
- Odour Threshold : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
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| | | |
|--|---|---|
| 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 |
| Flash point | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 10,5 - 12,5 |
| 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 |
| Relative density | : | No data available |
| Density | : | 0,950 - 1,150 g/cm ³ |
| Relative vapour density | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

9.2 Other information

| | | |
|----------------------|---|--|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | No data available |
| Molecular weight | : | No data available |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Acids

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

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

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

Serious eye damage/eye irritation

Causes serious eye damage.

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

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
Application Route: Ingestion
Method: OECD Test Guideline 474
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

Reproductive toxicity

Suspected of damaging fertility.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

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
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

STOT - single exposure

Corrosive to the respiratory tract.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Enrofloxacin:

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

SAFETY DATA SHEET

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Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

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
Method : OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



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Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Enrofloxacin:

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

SECTION 12: Ecological information

12.1 Toxicity

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 (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)

SAFETY DATA SHEET

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Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
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LOEC: 15 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

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

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

12.2 Persistence and degradability

Components:

Disodium EDTA, dihydrate:

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

12.3 Bioaccumulative potential

Components:

Enrofloxacin:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

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

12.4 Mobility in soil

Components:

Enrofloxacin:

Distribution among environmental compartments : Koc: 5,55

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 1814
ADR : UN 1814
RID : UN 1814
IMDG : UN 1814
IATA : UN 1814

14.2 UN proper shipping name

ADN : POTASSIUM HYDROXIDE SOLUTION
ADR : POTASSIUM HYDROXIDE SOLUTION
RID : POTASSIUM HYDROXIDE SOLUTION
IMDG : POTASSIUM HYDROXIDE SOLUTION
(Enrofloxacin)
IATA : Potassium hydroxide solution

14.3 Transport hazard class(es)

| | Class | Subsidiary risks |
|-------------|-------|------------------|
| ADN | : 8 | |
| ADR | : 8 | |
| RID | : 8 | |
| IMDG | : 8 | |
| IATA | : 8 | |

14.4 Packing group

ADN
Packing group : II
Classification Code : C5
Hazard Identification Number : 80
Labels : 8

ADR
Packing group : II
Classification Code : C5
Hazard Identification Number : 80
Labels : 8
Tunnel restriction code : (E)

RID
Packing group : II
Classification Code : C5
Hazard Identification Number : 80
Labels : 8

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

IMDG

Packing group : II
Labels : 8
EmS Code : F-A, S-B

IATA (Cargo)

Packing instruction (cargo aircraft) : 855
Packing instruction (LQ) : Y840
Packing group : II
Labels : Corrosive

IATA (Passenger)

Packing instruction (passenger aircraft) : 851
Packing instruction (LQ) : Y840
Packing group : II
Labels : Corrosive

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version 3.4 Revision Date: 30.09.2023 SDS Number: 9749474-00007 Date of last issue: 04.04.2023
Date of first issue: 13.10.2021

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

| | | Quantity 1 | Quantity 2 |
|----|-----------------------|------------|------------|
| E1 | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : 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 H-Statements

H290 : May be corrosive to metals.
H302 : Harmful if swallowed.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
H332 : Harmful if inhaled.
H361f : Suspected of damaging fertility.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

- H372 : Causes damage to organs through prolonged or repeated exposure.
- H373 : May cause damage to organs through prolonged or repeated exposure.
- H400 : Very toxic to aquatic life.
- H410 : Very toxic to aquatic life with long lasting effects.
- EUH014 : Reacts violently with water.
- EUH071 : Corrosive to the respiratory tract.

Full text of other abbreviations

- Acute Tox. : Acute toxicity
- Aquatic Acute : Short-term (acute) aquatic hazard
- Aquatic Chronic : Long-term (chronic) aquatic hazard
- Eye Dam. : Serious eye damage
- Met. Corr. : Corrosive to metals
- Repr. : Reproductive toxicity
- Skin Corr. : Skin corrosion
- STOT RE : Specific target organ toxicity - repeated exposure
- FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
- FOR-2011-12-06-1358 / T : Ceiling

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.4 | 30.09.2023 | 9749474-00007 | Date of first issue: 13.10.2021 |

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/>

Classification of the mixture:

| | |
|-------------------|-------|
| Acute Tox. 4 | H302 |
| Skin Corr. 1A | H314 |
| Eye Dam. 1 | H318 |
| Repr. 2 | H361f |
| STOT RE 1 | H372 |
| Aquatic Acute 1 | H400 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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.

NO / EN