

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
Date of first issue: 26.01.2017

SECTION 1. IDENTIFICATION

Product name : Enrofloxacin / Diclofenac Liquid Formulation

Manufacturer or supplier's details

Company : MSD

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

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Category 1

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

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

Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)


Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

- Hazard pictograms : 
- Signal Word : Danger
- Hazard Statements : H303 May be 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.
 H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
 H410 Very toxic to aquatic life with long lasting effects.
- Precautionary Statements : **Prevention:**
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe mist or vapors.
 P264 Wash skin thoroughly after handling.
 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.
 P312 Call a POISON CENTER/ doctor if you feel unwell.
 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.

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|------------|-----------------------|
| Enrofloxacin | 93106-60-6 | >= 10 -< 20 |
| Benzyl alcohol | 100-51-6 | >= 5 -< 10 |
| Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate | 15307-79-6 | >= 1 -< 2,5 |

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
 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 center 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.
 May be 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.

SECTION 5. FIRE-FIGHTING MEASURES

Enrofloxacin / Diclofenac Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 01.10.2022 |
| 4.0 | 04.04.2023 | 1241617-00017 | Date of first issue: 26.01.2017 |

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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
Chlorine compounds
Nitrogen oxides (NO_x)
Sodium oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
-

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

- 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 vapors.
 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.
 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 labeled 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
 Self-reactive substances and mixtures
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|------------|-------------------------------|--|----------|
| Enrofloxacin | 93106-60-6 | TWA | 0.2 mg/m ³ (OEB 2) | Internal |
| Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate | 15307-79-6 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Further information: Skin | | | | |

- 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 : Combined particulates and organic vapor type
- Hand protection : Chemical-resistant gloves

Enrofloxacin / Diclofenac Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 01.10.2022 |
| 4.0 | 04.04.2023 | 1241617-00017 | Date of first issue: 26.01.2017 |

- 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.
-

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Color : light yellow
- Odor : No data available
- Odor Threshold : No data available
- pH : 10,5 - 11,5
(as aqueous solution)
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : Not applicable
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapor pressure : No data available
- Relative vapor density : No data available

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
Date of first issue: 26.01.2017

Relative density : No data available

Density : 1,07 - 1,08 g/cm³

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents
Acids

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

May be harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 2.626 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Method: Calculation method

Components:**Enrofloxacin:**

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg
 LD50 (Rat): > 5.000 mg/kg
 LD50 (Mouse): > 5.000 mg/kg
 Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg
 Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l
 Exposure time: 4 h
 Test atmosphere: dust/mist
 Method: OECD Test Guideline 403

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg
 LD50 (Mouse): 170 - 389 mg/kg
 Acute toxicity (other routes of administration) : LD50 (Rat): 97 - 161 mg/kg
 Application Route: Intravenous
 LD50 (Mouse): 92 - 147 mg/kg
 Application Route: Intravenous

Skin corrosion/irritation

Causes severe burns.

Components:**Enrofloxacin:**

Result : No skin irritation

Benzyl alcohol:

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : irritating

Serious eye damage/eye irritation

Causes serious eye damage.

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Components:**Enrofloxacin:**

|||Result : Mild eye irritation

Benzyl alcohol:

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

|||Result : Mild eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Enrofloxacin:**

|||Test Type : Maximization Test
 |||Routes of exposure : Dermal
 |||Species : Guinea pig
 |||Result : Not a skin sensitizer.

Benzyl alcohol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**Enrofloxacin:**

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

|||Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse
 Result: negative

Test Type: Mammalian bone marrow sister chromatid exchange
 Species: Hamster
 Result: negative

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Test Type: Chromosomal aberration
 Species: Rat
 Result: negative

Benzyl alcohol:

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

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

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

Test Type: Mouse Lymphoma
 Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration
 Species: CHO
 Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Enrofloxacin:**

Species : Rat
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Species : Mouse
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Benzyl alcohol:

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
 Application Route : Oral

Enrofloxacin / Diclofenac Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 01.10.2022 |
| 4.0 | 04.04.2023 | 1241617-00017 | Date of first issue: 26.01.2017 |

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

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No fetotoxicity., No teratogenic effects.

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

Benzyl alcohol:

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

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Result: No effects on fertility.

Effects on fetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 1 mg/kg body weight
 Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: LOAEL: 5 mg/kg body weight
 Result: Embryo-fetal toxicity., No teratogenic effects.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.
 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:**Enrofloxacin:**

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
 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

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Species : Cat
 NOAEL : 25 mg/kg
 Application Route : Oral
 Exposure time : 30 Days
 Remarks : No significant adverse effects were reported

Benzyl alcohol:

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
 LOAEL : 0,25 mg/kg
 Application Route : Oral
 Exposure time : 98 w
 Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species : Dog
 LOAEL : 1 mg/kg
 Application Route : Oral
 Exposure time : 12 w
 Target Organs : Blood

Species : Baboon
 NOAEL : 0,5 mg/kg
 LOAEL : 5 mg/kg
 Application Route : Oral
 Exposure time : 52 w
 Target Organs : Gastrointestinal tract, Blood
 Symptoms : constipation, Diarrhea

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Ingestion : Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

SECTION 12. ECOLOGICAL INFORMATION

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

| | | |
|--|---|---|
| Toxicity to fish | : | LC50 (<i>Lepomis macrochirus</i> (Bluegill sunfish)): 79,5 mg/l Exposure time: 96 h |
| | | LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 196 mg/l Exposure time: 96 h |
| | | LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (<i>Hyalella azteca</i> (Amphipod)): > 206 mg/l Exposure time: 96 h |
| | | EC50 (<i>Daphnia magna</i> (Water flea)): 79,9 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 3,1 mg/l Exposure time: 72 h |
| | | EC50 (<i>Microcystis aeruginosa</i> (blue-green algae)): 0,049 mg/l Exposure time: 5 d |
| M-Factor (Acute aquatic toxicity) | : | 10 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (<i>Daphnia magna</i> (Water flea)): 9,8 mg/l Exposure time: 21 d |
| | | NOEC (<i>Daphnia magna</i> (Water flea)): 5 mg/l Exposure time: 21 d |
| | | LOEC (<i>Daphnia magna</i> (Water flea)): 15 mg/l Exposure time: 21 d |
| M-Factor (Chronic aquatic toxicity) | : | 10 |

Benzyl alcohol:

| | | |
|---|---|--|
| Toxicity to fish | : | LC50 (<i>Pimephales promelas</i> (fathead minnow)): 460 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (<i>Daphnia magna</i> (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 80,1 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 71,9 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49,2 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,32 mg/l
 Exposure time: 32 d
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211

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

Biodegradability : Result: Readily biodegradable.
 Biodegradation: 92 - 96 %
 Exposure time: 14 d

Bioaccumulative potential**Components:****Enrofloxacin:**

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

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
 Date of first issue: 26.01.2017

Benzyl alcohol:

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Partition coefficient: n-octanol/water : log Pow: 4,51

Mobility in soil**Components:****Enrofloxacin:**

Distribution among environmental compartments : Koc: 5,55

Other adverse effects

No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Enrofloxacin)
 Class : 9
 Packing group : III
 Labels : 9

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
 Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Enrofloxacin / Diclofenac Liquid Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1241617-00017 Date of last issue: 01.10.2022
Date of first issue: 26.01.2017

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Enrofloxacin)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 04.04.2023
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Full text of other abbreviations

Enrofloxacin / Diclofenac Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 01.10.2022 |
| 4.0 | 04.04.2023 | 1241617-00017 | Date of first issue: 26.01.2017 |

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AR / Z8