1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Enrofloxacin / Diclofenac Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

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

GHS Classification

Acute toxicity (Oral): Category 5
Skin corrosion/irritation: Category 3
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
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Hazard pictograms:

Signal word: Danger

Hazard statements:
H303 May be harmful if swallowed.
H316 Causes mild skin irritation.
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 vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P275 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 IF skin irritation occurs: Get medical advice/ attention.
P391 Collect spillage.

Response:
P405 Store locked up.

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

Other hazards which do not result in classification:
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrofloxacin</td>
<td>93106-60-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
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. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May be harmful if swallowed. Causes mild skin irritation. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
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: In the event of fire, wear self-contained breathing apparatus.

| Benzyl alcohol | 100-51-6 | >=5 - <10 |
| Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate | 15307-79-6 | >=1 - <2.5 |
6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions:
- Discharge into the environment must be avoided.
- 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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Avoid inhalation of vapour or mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Take care to prevent spills, waste and minimize release to the environment.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

<table>
<thead>
<tr>
<th>Form of exposure</th>
<th>(Form of exposure)</th>
<th>TWA</th>
<th>Permissible concentration</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrofloxacin</td>
<td>93106-60-6</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit 1000 µg/100 cm² Internal

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 vapour type

Hand protection: Chemical-resistant gloves

Eye protection: Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: light yellow

Odour: No data available

Odour Threshold: No data available

pH: 10.5 - 11.5
## Enrofloxacin / Diclofenac Liquid Formulation

**Version:** 2.3  
**Revision Date:** 23.03.2020  
**SDS Number:** 1241629-00010  
**Date of last issue:** 13.09.2019  
**Date of first issue:** 26.01.2017

*(as aqueous solution)*

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
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<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.07 - 1.08 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### 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.
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>2.3</td>
<td>23.03.2020</td>
<td>1241629-00010</td>
<td>13.09.2019</td>
<td>26.01.2017</td>
</tr>
</tbody>
</table>

Conditions to avoid: None known.
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
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
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 mild skin irritation.

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
Not classified based on available information.

Components:

Enrofloxacin:
Result : Mild eye irritation

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Result : Mild eye irritation

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.
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: 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:
Species: Mouse
Result: negative

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

Genotoxicity in vivo:
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:
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
Exposure time: 2 Years
Result: negative

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

Reproductive toxicity
Suspected of damaging fertility.

Components:

Enrofloxacin:
Effects on fertility: Test Type: Two-generation study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 15 mg/kg body weight
Result: Effects on fertility, alteration in sperm morphology

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

**Effects on foetal development:**  
Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects  
Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 5 mg/kg body weight  
Result: Embryo-foetal 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.
### Enrofloxacin / Diclofenac Liquid Formulation

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enrofloxacin:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>cartilage, Testis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
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<td></td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

<table>
<thead>
<tr>
<th>Components</th>
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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enrofloxacin:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>36 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>150 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Dog</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>3 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>9.6 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>cartilage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Cat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>25 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>30 Days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **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                         |                             |                             |                             |
| NOAEL              | 0.25 mg/kg                  |                             |                             |                             |
| Application Route  | Oral                        |                             |                             |                             |
| Exposure time      | 98 w                        |                             |                             |                             |
| Target Organs      | Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate |                             |                             |                             |
| Species            | Dog                         |                             |                             |                             |
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 1241629-00010 Date of last issue: 13.09.2019 Date of first issue: 26.01.2017

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>1 mg/kg</th>
</tr>
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<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 w</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Baboon</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
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</tr>
<tr>
<td>Exposure time</td>
<td>52 w</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract, Blood</td>
</tr>
<tr>
<td>Symptoms</td>
<td>constipation, Diarrhoea</td>
</tr>
</tbody>
</table>

**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, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Enrofloxacin:**
- Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l Exposure time: 96 h
  - LC50 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l Exposure time: 96 h
  - LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (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
**SAFETY DATA SHEET**

**Enrofloxacin / Diclofenac Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>2.3</td>
<td>23.03.2020</td>
<td>1241629-00010</td>
<td>13.09.2019</td>
<td>26.01.2017</td>
</tr>
</tbody>
</table>

EC50 (Microcystis aeruginosa (blue-green algae)): 0.049 mg/l
Exposure time: 5 d

**M-Factor (Acute aquatic toxicity):** 10

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

- **NOEC:** 9.8 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)

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

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

**M-Factor (Chronic aquatic toxicity):** 10

**Benzyl alcohol:**

**Toxicity to fish:**

- LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
  Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**

- EC50 (Daphnia magna (Water flea)): 230 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants:**

- EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

- NOEC: 51 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  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:**

- EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9
plants

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: 0.32 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

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

Persistence and degradability

Components:

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

Bioaccumulative potential

Components:

Enrofloxacin:
Partition coefficient: n-octanol/water: log Pow: 0.5

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

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
13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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
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 IMO instruments
Not applicable for product as supplied.

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

15. REGULATORY INFORMATION

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

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

16. OTHER INFORMATION

**Further information**


Date format: dd.mm.yyyy

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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 Tem-
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 1241629-00010 Date of last issue: 13.09.2019

Date of first issue: 26.01.2017

perature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Trans-
portation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - Unit-
ed Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;
vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials In-
formation System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, infor-
mation 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 mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

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