SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Version: 3.4  Revision Date: 13.09.2019  SDS Number: 1239759-00010  Date of last issue: 24.04.2019
Date of first issue: 26.01.2017

Section 1: Identification

Product name: Enrofloxacin / Diclofenac Liquid Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
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

Section 2: Hazard identification

GHS Classification
Reproductive toxicity: Repr.2
Specific target organ toxicity - repeated exposure: STOT RE1 (cartilage, Testis)
Specific target organ toxicity - repeated exposure: STOT RE2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements: 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.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Enrofloxacin</td>
<td>93106-60-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

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.
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 : 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.

### Section 5: Fire-fighting measures

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td></td>
<td>Chlorine compounds</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Sodium oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters</td>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<td>Hazchem Code</td>
<td>Use personal protective equipment.</td>
</tr>
<tr>
<td></td>
<td>3Z</td>
</tr>
</tbody>
</table>

### Section 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. |
Section 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.

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.

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.

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA (Vapour and particulates)</td>
<td>150 ppm 474 mg/m³</td>
<td>NZ OEL</td>
</tr>
<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-dichloro-phenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td>Wipe limit 1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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 Material: Chemical-resistant gloves

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

**Section 9: Physical and chemical properties**

Appearance: liquid

Colour: light yellow

Odour: No data available

Odour 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

Vapour pressure: No data available
Relative vapour density  :  No data available
Relative density  :  No data available
Density  :  1.07 - 1.08 g/cm³
Solubility(ies)  
Water solubility  :  soluble
Partition coefficient: n-octanol/water  :  Not applicable
Auto-ignition temperature  :  No data available
Decomposition temperature  :  No data available
Viscosity  
Viscosity, kinematic  :  No data available
Explosive properties  :  Not explosive
Oxidizing properties  :  The substance or mixture is not classified as oxidizing.
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
Exposure routes  :  Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity  :  Acute toxicity estimate: > 2,000 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:**

**Propylene glycol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity:
  - LC50 (Rabbit): > 159 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**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**
- Not classified based on available information.

**Components:**

**Propylene glycol:**
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
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:
Propylene glycol: 
Species : Rabbit 
Result : No eye irritation 
Method : OECD Test Guideline 405

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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Propylene glycol: 
Test Type : Maximisation Test 
Exposure routes : Skin contact 
Species : Guinea pig 
Result : negative
<table>
<thead>
<tr>
<th>Components</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Specie(s)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrofloxacin:</td>
<td>Maximisation Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Not a skin sensitizer.</td>
</tr>
<tr>
<td>Benzyl alcohol:</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
<tr>
<td>Chronic toxicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified based on available information.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrofloxacin:</td>
<td>Test Type: Chromosomal aberration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol:</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Mammalian bone marrow sister chromatid exchange Species: Hamster Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration Species: Rat Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzy alcohol:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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:**

**Propylene glycol:**  
Species: Rat  
Application Route: Ingestion  
Exposure time: 2 Years  
Result: negative

**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
### Reproductive toxicity
Suspected of damaging fertility.

### Components:

#### Propylene glycol:
- **Effects on fertility**: Test Type: Three-generation reproduction toxicity study  
  Species: Mouse  
  Application Route: Ingestion  
  Result: negative

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

#### 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

---

**Application Route**: Oral  
**Exposure time**: 2 Years  
**Result**: negative

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**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>
</thead>
</table>
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.

**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:**

**Propylene glycol:**
- Species: Rat, male
- NOAEL: 1,700 mg/kg
- Application Route: Ingestion
- Exposure time: 2 yr
### Enrofloxacin:

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

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1.072 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>28 Days</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.25 mg/kg</td>
<td>98 w</td>
<td>Oral</td>
<td>98 w</td>
<td>Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate</td>
</tr>
<tr>
<td>Dog</td>
<td>1 mg/kg</td>
<td></td>
<td>Oral</td>
<td>12 w</td>
<td>Blood</td>
</tr>
<tr>
<td>Baboon</td>
<td>0.5 mg/kg</td>
<td>52 w</td>
<td>Oral</td>
<td>52 w</td>
<td>Gastrointestinal tract, Blood</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

Section 12: Ecological information

**Ecotoxicity**

**Components:**

**Propylene glycol:**
Toxicity to fish: LC50 (Onchorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

**Enrofloxacin:**
Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l
Exposure time: 96 h

LC50 (Onchorhynchus 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

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

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

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

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

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

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

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

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:
Propylene glycol:
Biodegradability: Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F

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

Bioaccumulative potential

Components:
Propylene glycol:
Partition coefficient: n-octanol/water: log Pow: -1.07

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

Other adverse effects
No data available
Section 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.

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
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.

National Regulations

NZS 5433
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Enrofloxacin)
Class: 9
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Version 3.4  Revision Date: 13.09.2019  SDS Number: 1239759-00010  Date of last issue: 24.04.2019
Date of first issue: 26.01.2017

Packing group: III
Labels: 9
Hazchem Code: 3Z

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

Section 16: Other information

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

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 Organization 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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