SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

SECTION 1. IDENTIFICATION

Product name : Enrofloxacin / Diclofenac Liquid Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Skin corrosion : Category 1
Serious eye damage : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 1 (cartilage, Testis, Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
Hazard pictograms

Signal Word : Danger
Hazard Statements : H314 Causes severe skin burns and eye damage.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs (cartilage, Testis, 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.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a POISON CENTER.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.
P305 + P351 + P338 + P310 IF IN YES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.
P308 + P313 IF exposed or concerned: Get medical attention. P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<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; 50</td>
<td></td>
</tr>
<tr>
<td>Enrofloxacin</td>
<td>93106-60-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 5 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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. Causes serious eye damage. Suspected of damaging fertility. Suspected of damaging the unborn child. 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

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 (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 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).
Enrofloxacin / Diclofenac Liquid Formulation

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/PERSOANL PROTECTION section.

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

<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>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</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>Benzyl alcohol</td>
<td>100-51-6</td>
<td>TWA</td>
<td>10 ppm</td>
<td>US WEEL</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>
</tbody>
</table>

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
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>light yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>10.5 - 11.5 (as aqueous solution)</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</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>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor 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</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: 2,626 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 84 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:

Propylene glycol:
Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 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
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:  

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
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Version: 5.4
Revision Date: 04/04/2023
SDS Number: 1239761-00017
Date of last issue: 10/01/2022
Date of first issue: 01/26/2017

**Serious eye damage/eye irritation**
Causes serious eye damage.

**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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Propylene glycol:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

**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:

Propylene glycol:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

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

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

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

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

Test Type: Chromosomal aberration
Species: Rat
Result: negative

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
## 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>
</thead>
<tbody>
<tr>
<td>5.4</td>
<td>04/04/2023</td>
<td>1239761-00017</td>
<td>10/01/2022</td>
<td>01/26/2017</td>
</tr>
</tbody>
</table>

### Genotoxicity in vivo

<table>
<thead>
<tr>
<th>Test Type:</th>
<th>Species:</th>
<th>Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosomal aberration</td>
<td>CHO</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Carcinogenicity

Not classified based on available information.

### Components:

#### Propylene glycol:

<table>
<thead>
<tr>
<th>Species:</th>
<th>Application Route:</th>
<th>Exposure time:</th>
<th>Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Enrofloxacin:

<table>
<thead>
<tr>
<th>Species:</th>
<th>Application Route:</th>
<th>Exposure time:</th>
<th>Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Species:</th>
<th>Application Route:</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Ingestion</td>
<td>103 weeks</td>
<td>OECD Test Guideline 451</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species:</th>
<th>Application Route:</th>
<th>Exposure time:</th>
<th>Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>

### IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

### OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

### NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
Reproductive toxicity
Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

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

Effects on fetal development:
Test Type: Embryo-fetal 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 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.

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

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
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 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, 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 y

**Enrofloxacin**:
- Species: Rat
- NOAEL: 36 mg/kg
- LOAEL: 150 mg/kg
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Testis
Species: Dog
NOAEL: 3 mg/kg
LOAEL: 9.6 mg/kg

Application Route: Oral
Exposure time: 13 Weeks
Target Organs: cartilage
Species: Cat
NOAEL: 25 mg/kg

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Propylene glycol:
Toxicity to fish:
LC50 (Oncorhynchus 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 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l
Exposure time: 96 h

LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Hyalella azteca (Amphipod)): > 206 mg/l
Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 79.9 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)): 3.1 mg/l
Exposure time: 72 h

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 9.8 mg/l
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to fish</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrofloxacin / Diclofenac Liquid Formulation</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l</td>
<td>5 mg/l</td>
<td>21 d</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): 230 mg/l</td>
<td>15 mg/l</td>
<td>21 d</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l</td>
<td>230 mg/l</td>
<td>48 h</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l</td>
<td>51 mg/l</td>
<td>21 d</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l</td>
<td>0.32 mg/l</td>
<td>32 d</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
aquatic invertebrates (Chronic toxicity)  
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

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
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.

Domestic regulation

49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Enrofloxacin)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Enrofloxacin)
Remarks: Above applies only to containers over 119 gallons or 450 liters.
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Skin corrosion or irritation
- Serious eye damage or eye irritation

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Water 7732-18-5
- Propylene glycol 57-55-6
- Enrofloxacin 93106-60-6
- Benzyl alcohol 100-51-6

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

SECTION 16. OTHER INFORMATION

Further information
NFPA 704:

- **Health**: 3
- **Flammability**: 1
- **Instability**: 0
- **Special hazard**:

HMIS® IV:

- **HEALTH**: *
- **FLAMMABILITY**: 3
- **PHYSICAL HAZARD**: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
- US WEEL / TWA: 8-hr TWA

**Abbreviations**

- AIIIC - Australian Inventory of Industrial Chemicals
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DOT - Department of Transportation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- EHS - Extremely Hazardous Substance
- 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
- HMIS - Hazardous Materials Identification System
- 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
- MSHA - Mine Safety and Health Administration
- n.o.s. - Not Otherwise Specified
- NFPA - National Fire Protection Association
- NO(A)EC - No Observed (Adverse) Effect Concentration
- NO(A)EL - No Observed (Adverse) Effect Level
- NOELR - No Observable Effect Loading Rate
- 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
- RCRA - Resource Conservation and Recovery Act
- RO - Reportable Quantity
- SADT - Self-Accelerating Decomposition Temperature
- SAR - Superfund Amendments and Reauthorization Act
- SDS - Safety Data Sheet
- TCSI - Taiwan Chemical Substance Inventory
- TSCA - Toxic Substances Control Act
SAFETY DATA SHEET

Enrofloxacin / Diclofenac Liquid Formulation

Version 5.4  Revision Date: 04/04/2023  SDS Number: 1239761-00017  Date of last issue: 10/01/2022  Date of first issue: 01/26/2017

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023

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.

US / Z8