Section 1: Identification

Product name: Enrofloxacin (2.5%) 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

Specific target organ toxicity - repeated exposure: STOT RE2 (cartilage, Testis)

GHS label elements

Hazard pictograms: 

Signal word: Warning
Hazard statements: H373 May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.

Precautionary statements

Prevention:
P260 Do not breathe mist or vapours.
Response:
P314 Get medical advice/attention if you feel unwell.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.
SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

Version 4.6   Revision Date: 09/13/2019   SDS Number: 633922-00012   Date of last issue: 24.04.2019
Date of first issue: 27.04.2016

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrofloxacin</td>
<td>CAS-No. 93106-60-6</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>CAS-No. 100-51-6</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 soap and 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 cause 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

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
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
SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

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 spills cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed 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: Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. 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,
Conditions for safe storage:
- Keep in properly labelled containers.
- 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>Enrofloxacin</td>
<td>93106-60-6</td>
<td>TWA</td>
<td>0.2 mg/m3 (OEB 2)</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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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 : No data available
Solubility(ies) Water solubility : No data available
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
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:
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

Skin corrosion/irritation
Not classified based on available information.

Components:
Enrofloxacin:
Result: No skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Serious eye damage/eye irritation
Not classified based on available information.

Components:
Enrofloxacin:
Result: Mild eye irritation

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

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.

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

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

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

Test Type: Mammalian bone marrow sister chromatid ex-
change
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

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

Reproductive toxicity
Not classified based on available information.

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
SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

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.

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.

Components:

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

Repeated dose toxicity

Components:

Enrofloxacin:
Species: Rat
NOAEL: 36 mg/kg
LOAEL: 150 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Testis
Species: Dog
## SAFETY DATA SHEET

### Enrofloxacin (2.5%) 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>

- **NOAEL**: 3 mg/kg
- **LOAEL**: 9.6 mg/kg
- **Application Route**: Oral
- **Exposure time**: 13 Weeks
- **Target Organs**: cartilage

**Species**: Cat

- **NOAEL**: 25 mg/kg
- **Application Route**: Oral
- **Exposure time**: 30 Days

**Remarks**: No significant adverse effects were reported

### Benzyl alcohol:

**Species**: Rat

- **NOAEL**: 1.072 mg/l
- **Application Route**: Inhalation (dust/mist/fume)
- **Exposure time**: 28 Days

**Method**: OECD Test Guideline 412

**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

### Section 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
<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l</td>
<td>EC50 (Daphnia magna (Water flea)): 230 mg/l</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l</td>
<td>NOEC (Daphnia magna (Water flea)): 51 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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:**
SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

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

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
Enrofloxacin (2.5%) Formulation

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
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
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.

NZ / EN