SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Enrofloxacin (2.5%) Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 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. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Specific target organ toxicity - repeated exposure : Category 2 (cartilage, Testis)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms : ⚠ ⚖
Signal Word : Warning
Hazard Statements : H373 May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements : Prevention:
P273 Avoid release to the environment.
Response:
P314 Get medical advice/ attention if you feel unwell.
P391 Collect spillage.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>Enrofloxacin</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Benzyl alcohol</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></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.
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 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 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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items...
employed in the cleanup of releases. You will need to
determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
Avoid inhalation of vapor 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,
appropriate degowning and decontamination procedures,
industrial hygiene monitoring, medical surveillance and the
use of administrative controls.

Conditions for safe storage:
Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents
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>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 vapor 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
- **Color**: No data available
- **Odor**: No data available
- **Odor Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
Density: No data available

Solubility(ies):
Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity:
Viscosity, kinematic: No data available

Explosive properties: Not explosive

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

Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
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: > 5,000 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

**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 sensitization**

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

**Respiratory sensitization**
- Not classified based on available information.
Components:

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

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

Germ cell mutagenicity
- Not classified based on available information.

Components:

Enrofloxacin:
- Genotoxicity in vitro: Test Type: Chromosomal aberration
  Result: positive
- Genotoxicity in vivo: Test Type: Micronucleus test
  Species: Mouse
  Result: negative
  Test Type: Mammalian bone marrow sister chromatid exchange
  Species: Hamster
  Result: negative
  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

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

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

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

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

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

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
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: $\text{LC50 (Lepomis macrochirus (Bluegill sunfish))}: 79.5 \text{ mg/l}$
Exposure time: 96 h

$\text{LC50 (Oncorhynchus mykiss (rainbow trout))}: > 196 \text{ mg/l}$
Exposure time: 96 h

$\text{LC50 (Oryzias latipes (Japanese medaka))}: > 100 \text{ mg/l}$
Exposure time: 96 h

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

$\text{EC50 (Daphnia magna (Water flea))}: 79.9 \text{ mg/l}$
Exposure time: 48 h

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

$\text{EC50 (Microcystis aeruginosa (blue-green algae))}: 0.049 \text{ mg/l}$
Exposure time: 5 d

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

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

$\text{NOEC (Daphnia magna (Water flea))}: 9.8 \text{ mg/l}$
Exposure time: 21 d

$\text{NOEC (Daphnia magna (Water flea))}: 5 \text{ mg/l}$
Exposure time: 21 d

$\text{LOEC (Daphnia magna (Water flea))}: 15 \text{ mg/l}$
Exposure time: 21 d

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

Benzyl alcohol:
Toxicity to fish: $\text{LC50 (Pimephales promelas (fathead minnow))}: 460 \text{ mg/l}$

11 / 15
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 (Daphnia magna (Water flea)): 51 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

Persistence and degradability

Components:

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

Bioaccumulative potential

Components:

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

Benzyl alcohol:
- 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. (1-Cyclopropyl-7-(1-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quino)
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. (1-Cyclopropyl-7-(1-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quino)
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

ANTT
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Enrofloxacin)

Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Potassium hydroxide

International Regulations

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

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

Full text of other abbreviations

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 Sys-
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.

BR / Z8