SAFETY DATA SHEET

Enrofloxacin (10%) Formulation

Version 6.3  Revision Date: 23.03.2020  SDS Number: 641496-00014  Date of last issue: 13.09.2019  Date of first issue: 27.04.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Enrofloxacin (10%) Formulation

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

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral): Category 5
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 1 (cartilage, Testis)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: 

Signal word: Danger
Hazard statements: H303 May be harmful if swallowed.
H361f Suspected of damaging fertility.
H372 Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

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.

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>Enrofloxacin</td>
<td>93106-60-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water.
## 5. FIREFIGHTING MEASURES

| Suitable extinguishing media | Water spray  
|                             | Alcohol-resistant foam  
|                             | Carbon dioxide (CO2)  
|                             | Dry chemical  
| Unsuitable extinguishing media | None known.  
| Specific hazards during firefighting | Exposure to combustion products may be a hazard to health.  
| Hazardous combustion products | Carbon oxides  
| 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 firefighters | In the event of fire, wear self-contained breathing apparatus.  
|                             | Use personal protective equipment.  

## 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 | Soak up with inert absorbent material.  

Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.  

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

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

Most important symptoms and effects, both acute and delayed:  
May be harmful if swallowed.  
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.
containment and cleaning up

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : Use only with adequate ventilation.
Advice on safe handling : 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.
Conditions for safe storage : Keep in properly labelled containers.
                           : Store locked up.
                           : Store in accordance with the particular national regulations.
Materials to avoid : Do not store with the following product types:
                   : Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (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 rec-
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.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Colour: No data available
Odour: No data available
Odour 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
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

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reac- 
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

Acute toxicity  
May be harmful if swallowed.  

Product:
Acute oral toxicity : Acute toxicity estimate: 4,793 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
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days
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

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  
Suspected of damaging fertility.

Components:

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

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

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

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

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

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

### STOT - single exposure
Not classified based on available information.

### STOT - repeated exposure
Causes 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
SAFETY DATA SHEET

Enrofloxacin (10%) Formulation

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Enrofloxacin:

Toxicity to fish
LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l
Exposure time: 96 h
LC50 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l
Exposure time: 96 h
LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
EC50 (Hyalella azteca (Amphipod)): > 206 mg/l
Exposure time: 96 h
EC50 (Daphnia magna (Water flea)): 79.9 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants
EC50 (Pseudokirchneriella subcapitata (green algae)): 3.1 mg/l
Exposure time: 72 h
EC50 (Microcystis aeruginosa (blue-green algae)): 0.049 mg/l
Exposure time: 5 d

M-Factor (Acute aquatic toxicity)
10

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
NOEC: 9.8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
NOEC: 5 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
LOEC: 15 mg/l
Exposure time: 21 d
### Species: Daphnia magna (Water flea)

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

### Benzyl alcohol:

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

**Toxicity to daphnia and other aquatic invertebrates:**
- **EC50** (Daphnia magna (Water flea)): 230 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

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

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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
- **NOEC**: 51 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

### 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
SAFETY DATA SHEET

Enrofloxacin (10%) Formulation

Mobility in soil

Components:

Enrofloxacin:
Distribution among environmental compartments : Koc: 5.55

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Enrofloxacin)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Enrofloxacin)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Enrofloxacin)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes
Transport in bulk according to IMO instruments
Not applicable for product as supplied.

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

15. REGULATORY INFORMATION

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

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

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OSHA - Occupational Safety and Health Administration; PEL - Permissible Exposure Limit; PNEC - Predicted No Effect Concentration; PVOC - Pesticides and Veterinary Drugs Act (Australia); QC - Quality Control; RP - Refractory Properties; RT - Room Temperature; SC - Standard Concentration; SD - Standard Deviation; SDS - Safety Data Sheet; TCD - Threshold Concentration for Detection; TEEL - Threshold Exposure Exposure Level; TEL - Threshold Exposure Limit; TLC - Total Lethal Concentration; UN - United Nations; USP - United States Pharmacopoeia; VMS - Vessel Manifestation System; WHO - World Health Organization; WLDL - Working Level Dose Limit; xylan - Xylan; ymo - Year of Manufacture; YW - Year of Warning; ZEBRA - ZEBRA Database (Australia); ZH - Zurich Norm; ZR - Zurich Requirement; ZTV - ZTV-udu (Germany); ZTV-VA (Germany); ZTV-VD (Germany); ZTV-VdU (Germany)
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.

IN / EN