SAFETY DATA SHEET
Enrofloxacin (10%) Formulation

Version 6.0  Revision Date: 2020/03/23  SDS Number: 633947-00014  Date of last issue: 2019/09/13
Revision Date: 2020/03/23  SDS Number: 633947-00014  Date of last issue: 2019/09/13

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Enrofloxacin (10%) Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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 : 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.
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P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Enrofloxacin</td>
<td>93106-60-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
<td>3-1011</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. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

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

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

Most important symptoms and effects, both acute and delayed: Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure.
Protection of first-aiders:
- First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:
- Treat symptomatically and supportively.

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 spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
7. HANDLING AND STORAGE

**Handling**

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.

Avoidance of contact: Oxidizing agents

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.

**Storage**

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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<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., dripless 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
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid
Colour: No data available
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: No data available
Decomposition temperature: No data available
pH: No data available
Evaporation rate: No data available
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
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
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

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
- Method: OECD Test Guideline 412
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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 (Hyaella 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 (Daphnia magna (Water flea)): 9.8 mg/l Exposure time: 21 d
    - NOEC (Daphnia magna (Water flea)): 5.0 mg/l Exposure time: 21 d
    - LOEC (Daphnia magna (Water flea)): 15 mg/l Exposure time: 21 d
  - **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 (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

Hazardous to the ozone layer
Not applicable

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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

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.
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Sheets. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations
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.

JP / EN