

Enrofloxacin 100 mg/mL Antimicrobial Injectable solution

Safety Data Sheet



Date of issue: 10 Nov 2023

Version:.00

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Enrofloxacin 100 mg/mL Antibacterial Injectable Solution

1.2. Intended Use of the Product

Use of the substance/mixture: For subcutaneous use in beef cattle, non-lactating dairy cattle and swine only. It is sterile, ready to use Injectable antimicrobial solution for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle while in Swine, it is indicated for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*.

1.3. Name, Address, and Telephone of the Responsible Party

Felix Pharmaceuticals Private Limited
25-28, North Wall Quay Dublin 1,
Republic of Ireland

1.4. Emergency Telephone Number

Emergency Number: contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is injectable solution for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

2.2. Label Elements

No labeling applicable

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/ INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture:

Name	CAS number	Approximate Quantity
Enrofloxacin (1-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid)	93106-60-6	10.0%
1-Butanol	71-36-3	3.0%
Benzyl alcohol	100-51-6	2.0%

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: If you feel unwell, seek medical advice.

First-aid Measures After Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

First-aid Measures After Skin Contact: If skin contact occurs, wash skin with soap and water. Get medical attention if irritation persists.

First-aid Measures After Eye Contact: If eye contact occurs, flush immediately with water for at least 15 minutes. Get medical attention if irritation persists.

First-aid Measures After Ingestion: Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries After Inhalation: Due to the product's final form, inhalation is an unlikely route of exposure.

Symptoms/Injuries After Skin Contact: None expected under normal conditions of use.

Symptoms/Injuries After Eye Contact: None expected under normal conditions of use.

Symptoms/Injuries After Ingestion: Pharmaceutical. Ingestion is likely to be harmful or have adverse effects

Chronic Symptoms: None expected under normal conditions of use

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4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

No additional information available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

5.2. Special Hazards Arising from the Substance or Mixture

Fire Hazard: Not considered flammable.

Explosion Hazard: Product itself is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Special Fire Fighting Procedure: Fire may cause evolution of: Carbon monoxide Carbon dioxide (CO₂). In the event of fire, wear self-contained breathing apparatus. Prevent fire extinguishing water from contaminating surface water or the ground water system.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid unnecessary contact with skin, eyes and clothing.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Avoid release to environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Dispose of waste in accordance with local, state and federal regulations

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Avoid contact with skin, eyes and clothing. Take measures to prevent the buildup of electrostatic charge.

Keep away from open flames, hot surfaces and sources of ignition. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Protect from direct sunlight. Do not refrigerate or freeze. Store at 20° to 25°C (68°-77°F), excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature]. Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

7.3. Specific End Use(s)

Antibacterial. For professional use only. Federal (U.S.A.) law restricts this drug to be used by or on the order of a licensed veterinarian.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

n-butanol

USA ACGIH	ACGIH TWA (ppm)	20 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	150 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	50 ppm
USA IDLH	US IDLH (ppm)	1400 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	300 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	100 ppm

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8.2. Exposure Controls

- Appropriate Engineering Controls** : Avoid creating or spreading dust. Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.
- Personal Protective Equipment** : Not generally required. The use of personal protective equipment may be necessary as conditions warrant.
- Hand Protection** : Wear protective gloves.
- Eye Protection** : If splashes are likely to occur, wear safety glasses with side-shields.
- Skin and Body Protection** : Wear suitable protective clothing if skin contact with drug product is possible.
- Respiratory Protection** : No protection equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and excavation may be required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

- Physical State** : Liquid
- Appearance** : Clear solution.
- Odor** : No data available
- Odor Threshold** : No data available
- pH** : No data available
- Evaporation Rate** : No data available
- Melting Point** : No data available
- Freezing Point** : No data available
- Boiling Point** : No data available
- Flash Point** : No data available
- Auto-ignition Temperature** : No data available
- Decomposition Temperature** : No data available
- Flammability (solid, gas)** : No data available
- Vapor Pressure** : No data available
- Relative Vapor Density at 20 °C** : No data available
- Relative Density** : No data available
- Solubility** : No data available
- Partition Coefficient: N-Octanol/Water** : No data available
- Viscosity** : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions.
- 10.3. Possibility of Hazardous Reactions:** None under normal conditions.
- 10.4. Conditions to Avoid:** Direct sunlight. Extremes of temperatures.
- 10.5. Hazardous Decomposition Products:** Decomposition will not occur under normal conditions

SECTION 11: TOXICOLOGICAL INFORMATION

- Acute Toxicity:**
- Oral LD₅₀ (rat) >5000 mg/kg (Enrofloxacin)
 - Oral LD₅₀ (rat): 790 mg/kg (n-butanol)
 - Oral LD₅₀ (rat): 1230 mg/kg (Benzyl alcohol)
 - Inhalation LC50 (rat) >2.937 mg/l, 4h (Enrofloxacin)
 - Inhalation LC50 (rat): 8000 ppm, 4h (n-butanol)
 - Inhalation LC50 (rat): > 4.178 mg/l/4h (Benzyl alcohol)
 - Dermal LD50 (rabbit) >2000 mg/kg (Enrofloxacin)
 - Dermal LD50 (rabbit): 3,400 mg/kg (n-butanol)
 - Dermal LD50 (rabbit) >2000 mg/kg (Benzyl alcohol)

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Local Effects: Skin: non-irritant to the skin. Non-sensitizing to the skin.

Reproductive Effects: Not Classified

Mutagenicity: None of the ingredients of the formulation have been shown to produce mutagenic effects.
Carcinogenic Effects: Enrofloxacin has been shown in animal tests to have no carcinogenic potential. Other ingredients are not classified as carcinogens.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity** No additional information available
- 12.2. Persistence and Degradability** No additional information available
- 12.3. Bio accumulative Potential** No additional information available
- 12.4. Mobility in Soil** No additional information available
- 12.5. Other Adverse Effects** No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

Transport according to all local, state and federal regulation

SECTION 15: REGULATORY INFORMATION

Enrofloxacin injectable solution is indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : Not Applicable

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

To the best of Felix's knowledge, the information contained here is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.