Product Name: Enroquin (enrofloxacin) Antibacterial Injectable Solution 2.27%

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SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name	Enroquin (enrofloxacin) Antibacterial Injectable Solution 2.27%
Synonyms	Not available
Proper shipping name	Not available
Other means of identification	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses	For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin. For professional use only. Federal (U.S.A.) law restricts this drug to be used by or on the order of a licensed veterinarian.
Uses advised against	Not for human use
1.3 Details of the supplier of the	substance or mixture
Registered company name	Dechra Veterinary Products
Address	7015 College Blvd Suite 525 Overland Park KS 66211 USA
Telephone	866-933-2472
Fax	Not available
Email	Not available
1.4 Emergency telephone numbers	
Dechra (US)	866-933-2472

## 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 an injectable solution for direct administration to the patient. Therefore, it is 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

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SECTION 3: C	OMPOSITION	I/INFORMATION ON THE INGREDIENTS
3.1 Substanc	es	
See section below for composition of Mixtures.		
3.2 Mixtures		
CAS No	%[weight]	Name
93106-60-6	2.27	enrofloxacin (1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-
		1,4-dihydro-4-oxo-3-quinolinecarboxylic acid)
71-36-3	3.0	<u>n-butanol</u>

## **SECTION 4: FIRST AID MEASURES**

#### 4.1 Description of first aid measures

#### General advice:

If you feel unwell, seek medical advice.

#### **Eye contact:**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if irritation persist.

#### Skin contact:

Wash off with soap and plenty of water. Consult a physician if irritation persist.

#### 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.

#### Ingestion:

Rinse mouth with water. Consult a physician.

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

#### Inhalation:

Due to the product's final form, inhalation is an unlikely route of exposure.

#### Skin contact:

None expected under normal conditions of use,

#### **Eve contact:**

None expected under normal conditions of use.

#### Ingestion:

Ingestion of the product is likely to be harmful or have adverse effects.

#### **Chronic symptoms:**

None expected under normal conditions of use.

## 4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

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#### **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 release of carbon monoxide, carbon dioxide. In the event of fire, wear self-contained breathing apparatus. Prevent fire. Prevent water from contaminating surface water or the ground water system.

## 5.3 Advice for fire-fighters:

**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 References to other sections

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

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SECTION 7: HANDLING AND STORAGE		
7.1 Precautions for sa	7.1 Precautions for safe handling	
	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 freeze. Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).	
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 C	ONTROLS / PERSONAL PRO	OTECTION
8.1 Control parameters		
n-butanol		
USA ACGIH	ACGIH TWA	20 ppm
USA NIOSH	NIOSH REL (ceiling)	150 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling)	50 ppm
USA IDLH	US IDLH	1400 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA)	300 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA)	100 ppm
8.2 Exposure controls		
Appropriate engineering		dust. Ensure adequate ventilation,
controls		Emergency eye wash fountains and
		ailable in the immediate vicinity of re all national/local regulations are
	observed.	re all flational/local regulations are
Personal protective	Not generally required. T	he use of personal protective
equipment	equipment may be necessary	as conditions warrant.
Hand protection	Wear protective gloves	
Eye protection	•	ur, wear safety glasses with side-
	shields.	
Skin and body protection	Wear suitable protective cloth is possible.	ing if skin contact with drug product
Respiratory protection		eeded under normal use conditions.
respiratory proteotion		eded or irritation is experienced,
	ventilation and excavation ma	

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#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1 Information on basic physical and chemical properties

Appearance: Clear colorless solution free

from visible foreign matter. **Physical state:** Liquid **Odor:** Not Available

Odor threshold: Not Available pH (as supplied): Not Available

Melting point / freezing point (degrees C):

Not Available

Initial boiling point and boiling range: Not

Available

Flash point: Not Applicable Evaporation rate: Not Available Flammability: Not Available

Upper / lower flammability or explosive

limits: Not Available

Vapor pressure: Not Available Relative density (at degrees C): Not

Available

Solubility in water and solvents (mg/l): Not

Available

Vapor density: Not Available

Auto ignition temperature (degrees C): Not

Applicable

**Decomposition temperature (degrees C):** 

Not Available

Viscosity (degrees C): Not Available

Explosive properties: None Oxidizing properties: None

Partition coefficient: Not Available Molecular weight: Not Applicable

Taste: Not Available

**Surface tension:** Not Available **Volatile component:** Not Available

Gas group: Not Available

pH as a solution: Not Available

VOC g/L: Not Available

Specific gravity @ 20 degrees C (water =

1): Not Available

## 9.2 Other information

No additional information available

10: REACTIVITY AND STABILITY	
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	Stable under recommended handling and storage conditions.
10.4 Conditions to avoid	Direct sunlight. Extremes of temperatures.
10.5 Hazardous decomposition products	Decomposition will not occur under normal conditions

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SECTION 11: TOXICOLOGICAL INFORMATION	
Acute toxicity	Oral LD <sub>50</sub> (rat) >5000 mg/kg (enrofloxacin)
	Oral LD <sub>50</sub> (rat): 790 mg/kg (n-butanol)
	Inhalation LC <sub>50</sub> (rat) >2.937 mg/l, 4h (enrofloxacin)
	Inhalation LC <sub>50</sub> (rat): 8000 ppm, 4h (n-butanol)
	Dermal LD <sub>50</sub> (rabbit) >2000 mg/kg (enrofloxacin)
	Dermal LD <sub>50</sub> (rabbit): 3,400 mg/kg (n-butanol)
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.

SEC	TION 12: ECOLOGICAL INFORMATION
12.1	Toxicity: No additional information available
12.2	Persistence and degradability: No additional information available
12.3	Bioaccumulative 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**

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

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#### **SECTION 16: OTHER INFORMATION**

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