

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Enroflox 2.27% Injection for Dogs

Product Code: ANADA 200-513

1.2. Intended Use of the Product

Use of the Substance/Mixture: Enroflox® (enrofloxacin) Injection for Dogs 2.27% indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

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

Supplier

Norbrook, Inc.

9401 Indian Creek Parkway – Ste. 680

Overland Park, KS 66210

Phone: 913 599 5777

Fax: 913 599 5766

Manufacturer

Norbrook Laboratories Ltd,

Station Works, Newry, Co.Down,

N.Ireland, BT35 6JP.

Telephone No. +44 (0)28 3026 4435

Fax No. +44 (0)28 3026 1721

E-Mail: enquiries@norbrook.co.uk

1.4. Emergency Telephone Number

Emergency Number : 913 599 5777

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Eye Dam. 1 H318

Resp. Sens. 1 H334

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.

H318 - Causes serious eye damage.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 - Wear protective gloves, protective clothing, and eye protection.

P284 - [In case of inadequate ventilation] wear respiratory protection .

P302+P352 - If on skin: Wash with plenty of water.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a poison center or doctor.

P321 - Specific treatment (see section 4 on this SDS).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

P363 - Wash contaminated clothing before reuse.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

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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	Product Identifier	%	GHS-US classification
1-Butanol	(CAS No) 71-36-3	Proprietary	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H336 STOT SE 3, H335
1-Cyclopropyl-7-(4-ethyl-1-piperaziny)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid	(CAS No) 93106-60-6	Proprietary	Resp. Sens. 1, H334 Skin Sens. 1, H317
Potassium hydroxide	(CAS No) 1310-58-3	Proprietary	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318

Full text of H-phrases: see section 16

The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret [29 CFR 1910.1200]

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Gently wash with plenty of soap and water followed by rinsing with water for at least 15 minutes. Call a POISON CENTER or doctor/physician if you feel unwell. Wash contaminated clothing before reuse.

First-aid Measures After Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 60 minutes. Immediately call a POISON CENTER or doctor/physician.

First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Causes serious eye damage. Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes serious eye damage. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision. Causes permanent damage to the cornea, iris, or conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion 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

If you feel unwell, seek medical advice (show the label where possible).

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 flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

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

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed. Avoid all contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or spray.

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 Personnel

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 the environment.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Absorb and/or contain spill with inert material, then place in suitable container. Clean up spills immediately and dispose of waste safely.

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

Precautions for Safe Handling: Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Store locked up. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 25 °C Max

7.3. Specific End Use(s)

Enroflox® (enrofloxacin) Injection for Dogs 2.27% indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

1-Butanol (71-36-3)		
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
Potassium hydroxide (1310-58-3)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³

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USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
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8.2. Exposure Controls

Appropriate Engineering Controls

: 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

: Avoid all unnecessary exposure. Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection

: In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

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 at standard temperature and pressure.
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition generates : Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

1-Butanol (71-36-3)	
LD50 Oral Rat	700 mg/kg
LD50 Dermal Rabbit	3402 mg/kg
LC50 Inhalation Rat	> 8000 ppm/4h

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1-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid (93106-60-6)	
LD50 Oral Rat	5000 mg/kg
Potassium hydroxide (1310-58-3)	
LD50 Oral Rat	333 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Causes serious eye damage.

Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes serious eye damage. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision. Causes permanent damage to the cornea, iris, or conjunctiva.

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

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

1-Butanol (71-36-3)	
LC50 Fish 1	1730 - 1910 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	1983 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	1740 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 2	1897 - 2072 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

1-Butanol (71-36-3)	
BCF Fish 1	0.64
Log Pow	0.785 (at 25 °C)
Potassium hydroxide (1310-58-3)	
Log Pow	0.65

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

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.

Additional Information: Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
1-Butanol (71-36-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Subject to reporting requirements of United States SARA Section 313	
EPA TSCA Regulatory Flag	T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule
SARA Section 313 - Emission Reporting	1.0 %
Potassium hydroxide (1310-58-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

1-Butanol (71-36-3)	
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List	
Potassium hydroxide (1310-58-3)	
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List	

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

Revision Date	: 06/16/2016
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness

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.
SDS US (GHS HazCom)