

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Enroflox Injection (10%)

Product Code: ANADA 200-495

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. Enroflox® 100 is a sterile, ready-to-use injectable antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent.

Cattle - Single-Dose Therapy: Enroflox 100 is indicated 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; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with M. haemolytica, P. multocida, H. somni and M. bovis.

Cattle - Multiple-Day Therapy: Enroflox 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni in beef and non-lactating dairy cattle.

Swine: Enroflox 100 is indicated for the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis and Streptococcus suis.

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

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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.

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-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid | (CAS No) 93106-60-6 | Proprietary | Resp. Sens. 1, H334 Skin Sens. 1, H317 |
| 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 |
| Benzyl alcohol | (CAS No) 100-51-6 | Proprietary | Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:vapor), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401 |

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

Full text of H-phrases: see section 16

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 After 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).

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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 flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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.

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 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 the environment.

6.3. Methods and Material 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. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

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)

For subcutaneous use in beef cattle, non-lactating dairy cattle and swine only. Enroflox[®] 100 is a sterile, ready-to-use injectable antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent.

Cattle - Single-Dose Therapy: Enroflox 100 is indicated 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; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with M. haemolytica, P. multocida, H. somni and M. bovis.

Cattle - Multiple-Day Therapy: Enroflox 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni in beef and non-lactating dairy cattle.

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Swine: Enroflox 100 is indicated for the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis and Streptococcus suis.

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).

| Benzyl alcohol (100-51-6) | | |
|---------------------------|--|-----------------------|
| USA AIHA | WEEL TWA (ppm) | 10 ppm |
| 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 |

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 |

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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

| Benzyl alcohol (100-51-6) | |
|--|--------------------------|
| LD50 Oral Rat | 1230 mg/kg |
| LD50 Dermal Rabbit | > 2000 mg/kg |
| LC50 Inhalation Rat | > 4.178 mg/l/4h |
| LC50 Inhalation Rat | 8.9 mg/l/4h |
| LC50 Inhalation Rat | > 5.4 mg/l/4h |
| 1-Butanol (71-36-3) | |
| LD50 Oral Rat | 700 mg/kg |
| LD50 Dermal Rabbit | 3402 mg/kg |
| LC50 Inhalation Rat | > 8000 ppm/4h |
| ATE (Oral) | 790.00 mg/kg body weight |
| 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 |

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

| Benzyl alcohol (100-51-6) | |
|---------------------------|--|
| LC50 Fish 1 | 460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) |
| EC50 Daphnia 1 | 23 mg/l (Exposure time: 48 h - Species: water flea) |
| LC 50 Fish 2 | 10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| ErC50 (algae) | 770 mg/l |
| 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) |
| LC 50 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]) |

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12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

| | |
|----------------------------------|------------------|
| Benzyl alcohol (100-51-6) | |
| Log Pow | 1.1 |
| 1-Butanol (71-36-3) | |
| BCF fish 1 | 0.64 |
| Log Pow | 0.785 (at 25 °C) |

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. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

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

| | |
|--|--|
| Enroflox Injection (10%) | |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |
| Benzyl alcohol (100-51-6) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| 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 % |

15.2 US State Regulations

| | |
|---|--|
| Benzyl alcohol (100-51-6) | |
| U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List | |
| 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 | |

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

Revision Date : 03/08/2016

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 (Inhalation:vapor) | Acute toxicity (inhalation:vapor) Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral) Category 4 |

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| | |
|-----------------|---|
| Aquatic Acute 2 | Hazardous to the aquatic environment - Acute Hazard Category 2 |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Flam. Liq. 3 | Flammable liquids Category 3 |
| Flam. Liq. 4 | Flammable liquids Category 4 |
| Resp. Sens. 1 | Respiratory sensitisation Category 1 |
| 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 |
| H227 | Combustible liquid |
| H302 | Harmful if swallowed |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H332 | Harmful if inhaled |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |
| H336 | May cause drowsiness or dizziness |
| H401 | Toxic to aquatic life |

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)