

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Oxytetracycline Injection 200

Product Code: NADA 200-306

1.2. Intended Use of the Product

Use of the substance/mixture: For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. Oxytetracycline Injection 200 is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline by injection.

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

Acute Tox. 4 (Oral) H302
 Eye Irrit. 2A H319
 Repr. 2 H361

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)

: Warning

Hazard Statements (GHS-US)

: H302 - Harmful if swallowed.
 H319 - Causes serious eye irritation.
 H361 - Suspected of damaging fertility or the unborn child.

Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
 P270 - Do not eat, drink or smoke when using this product.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P301+ P330+P312 - If swallowed: Rinse mouth. Call a poison center or doctor if you feel unwell.
 P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P337+P313 - If eye irritation persists: Get medical advice/attention.
 P405 - Store locked up.
 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

Oxytetracycline Injection 200

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
2-Pyrrolidinone	(CAS No) 616-45-5	**	Acute Tox. 4 (Oral), H302 Eye Irrit. 2A, H319
2-Naphthacencarboxamide, 4-(dimethylamino)-1,4,4a, 5,5a,6,11,12 a-octahydro-3,5,6,10,12,12a -hexahydroxy-6-methyl-1,11-dioxo-, dihydrate, [4S-(4.alpha., 4a.alpha.,5.alpha.,5a.alpha.,6.beta., 12a.alpha.)]-	(CAS No) 6153-64-6	**	Eye Irrit. 2A, H319 Repr. 2, H361
Magnesium oxide (MgO)	(CAS No) 1309-48-4	**	Not classified

** proprietary information

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 at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation persists.

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: Harmful if swallowed. Causes serious eye irritation. Suspected of damaging fertility or the unborn child. Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Harmful if swallowed. Symptoms may include: May cause gastrointestinal irritation.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

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.

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.

Oxytetracycline Injection 200

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

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. Do not freeze.

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

Storage Temperature: Max 30 °C

7.3. Specific End Use(s)

For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. Oxytetracycline Injection 200 is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline by injection.

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).

Magnesium oxide (MgO) (1309-48-4)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³ (inhalable fraction)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA IDLH	US IDLH (mg/m ³)	750 mg/m ³ (fume)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (fume, total particulate)

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. Safety glasses. Protective clothing. Insufficient ventilation: wear respiratory protection.



Oxytetracycline Injection 200

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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:** Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

Oxytetracycline Injection 200	
ATE (Oral)	819.96 mg/kg body weight
2-Pyrrolidinone (616-45-5)	
LD50 Oral Rat	328 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Oxytetracycline Injection 200

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Harmful if swallowed. Symptoms may include: May cause gastrointestinal irritation.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

2-Pyrrolidinone (616-45-5)

LC50 Fish 1	4600 - 10000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
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12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

2-Pyrrolidinone (616-45-5)

Log Pow	-0.71 (at 25 °C)
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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

Oxytetracycline Injection 200

SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard
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Magnesium oxide (MgO) (1309-48-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

2-Pyrrolidinone (616-45-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations

Magnesium oxide (MgO) (1309-48-4)

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

2-Pyrrolidinone (616-45-5)

U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

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

Revision Date : 02/08/2016

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Oxytetracycline Injection 200

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 2	Reproductive toxicity Category 2
H302	Harmful if swallowed
H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child

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)