

SAFETY DATA SHEETS

This SDS packet was issued with item:

078852849

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078707675

According to EC Regulation 1907/2006 (REACH)



PRODUCT SAFETY DATA SHEET

OXYTET 20 INJECTION

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

Product Name	Oxytet 20 Injection
Manufacturer	Norbrook Laboratories Ltd, Station Works, Newry, Co.Down, N.Ireland, BT35 6JP.
Supplier	Norbrook, Inc. 9733 Loiret Blvd Lenexa, KS 66219 Phone: 913 599 5777 Fax: 913 599 5766

2. HAZARDS IDENTIFICATION

Physical and Chemical Hazards	:	Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC.
Environmental Hazards	:	None known
Adverse Human Health Effects	:	There are no known adverse effects of exposure to Oxytet 20 Injection.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation	:	Preparation
Active Ingredients	:	Oxytetracycline Hydrochloride
Description	:	Antibacterial
Chemical Family	:	Tetracyclines

4. FIRST AID MEASURES

Inhalation	:	Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.
Skin Contact	:	Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.
Eyes Contact	:	Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
Ingestion	:	Do not induce vomiting. Seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media:	Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours.
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Fire and explosion hazards: None.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.
Environmental Precautions : Keep away from drains, surface-water, ground-water and soil.
Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.
Storage : Store in closed containers in a cool, dry, well-ventilated area, below 25°C and away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.
Keep container closed when not in use. Do not transfer contents to unlabelled containers. Use only with adequate ventilation. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Oxytetracycline Not Established

For pure oxytetracycline :

LD50 (Oral, mouse) 2240 mg/kg

LD50 (Oral, rat) 4800 mg/kg

Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Sterile aqueous solution
Colour : Clear, yellow/brown
Odour : None.

10. STABILITY AND REACTIVITY

Stability : Stable under normal temperatures and pressures.
Conditions to avoid : None known
Materials to avoid : None known

11. TOXICOLOGICAL INFORMATION

Exposure Effects (Acute)

Eye Contact : Direct contact of the solution with eyes can cause irritation.

Skin Contact	:	Prolonged or repeated contact with Oxytet 20 Injection may cause irritation and/or drying and cracking of the skin.
Inhalation	:	None known.
Ingestion	:	Oral toxicity of the Oxytet 20 Injection solution is low.

Exposure Effects (Chronic)

Unknown for the product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Both its mutagenicity and its teratogenicity are not known.

12. ECOLOGICAL INFORMATION

Data on the ecological implications for Oxytet 20 Injection is not yet available.

13. DISPOSAL CONSIDERATIONS

Product/Residues	:	Do not discharge the product material into surface or waste water. For disposal, use an incinerator licensed for chemical waste.
Package	:	Dispose of waste containers using regular disposal methods in accordance with local and national environmental regulations.

14. TRANSPORT INFORMATION

Land, Sea & Air Transport

ADR/RID, IMO/IMDG, IATA/ICAO, UN No. : Not applicable

15. REGULATORY INFORMATION

Labelling Information	:	None
Safety phrases	:	S2 Keep out of reach of children
	:	S7 Keep container tightly closed

16. OTHER INFORMATION

ML : 2000/01 For Animal Treatment Only

ANADA 200-452, approved by FDA

JINAD 011-068

Revision Date : 20/07/10
Revision No : 02
Printing Date : 20/07/2010

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories Limited will not be held liable for any damage resulting from the handling of or contact with the above product.

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

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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.

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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.



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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

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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.

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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)