

10789.



## Noromycin 300

### Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations  
Revision Date: 06/16/2016 Date of Issue: 06/16/2016

C36193  
C36194

Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Noromycin 300

**Product Code:** NADA 141-143

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Noromycin 300 (Oxytetracycline) Injection is a sterile, pre-constituted solution of the broad-spectrum antibiotic oxytetracycline dihydrate. For Use in Beef Cattle, Non-lactating Dairy Cattle, Calves, including Pre-ruminating (Veal) Calves in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., and *Histophilus* spp., infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*, foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by strains of staphylococcal and streptococcal organisms sensitive to oxytetracycline. Also, Noromycin 300 (Oxytetracycline) Injection is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*Pasteurella*) *haemolytica*. For use in swine in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. In sows Noromycin 300 is indicated as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

### 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 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)

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



Noromycin 300

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and 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
2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-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	Proprietary	Eye Irrit. 2A, H319 Repr. 2, H361
1,3-Dioxolan-4-ylmethanol	(CAS No) 5464-28-8	Proprietary	Eye Irrit. 2A, H319
Polyethylene glycol	(CAS No) 25322-68-3	Proprietary	STOT SE 3, H335
Magnesium oxide (MgO)	(CAS No) 1309-48-4	Proprietary	Not classified
Ethanolamine	(CAS No) 141-43-5	Proprietary	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:vapor), H332 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401 Aquatic Chronic 3, H412

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 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:** 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:** Ingestion is likely to be harmful or have adverse effects.

**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).



# Noromycin 300

Safety Data Sheet

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

## 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.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). 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. 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:** 30 °C Max

### 7.3. Specific End Use(s)

Noromycin 300 (Oxytetracycline) Injection is a sterile, pre-constituted solution of the broad-spectrum antibiotic oxytetracycline dihydrate. For Use in Beef Cattle, Non-lactating Dairy Cattle, Calves, including Pre-ruminating (Veal) Calves in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., and *Histophilus* spp., infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*, foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by strains of staphylococcal and streptococcal organisms sensitive to oxytetracycline. Also, Noromycin 300 (Oxytetracycline) Injection is indicated for the control of respiratory disease in



Noromycin 300

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

cattle at high risk of developing BRD associated with Mannheimia (Pasteurella) haemolytica. For use in swine in the treatment of bacterial enteritis (scours, colibacillosis) caused by Escherichia coli, pneumonia caused by Pasteurella multocida, and leptospirosis caused by Leptospira pomona. In sows Noromycin 300 is indicated as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by Escherichia coli.

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/m³)	10 mg/m³ (inhalable fraction)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA IDLH	US IDLH (mg/m³)	750 mg/m³ (fume)
USA OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (fume, total particulate)
Ethanolamine (141-43-5)		
USA ACGIH	ACGIH TWA (ppm)	3 ppm
USA ACGIH	ACGIH STEL (ppm)	6 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m³)	8 mg/m³
USA NIOSH	NIOSH REL (TWA) (ppm)	3 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m³)	15 mg/m³
USA NIOSH	NIOSH REL (STEL) (ppm)	6 ppm
USA IDLH	US IDLH (ppm)	30 ppm
USA OSHA	OSHA PEL (TWA) (mg/m³)	6 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	3 ppm
Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m³)	10 mg/m³ (MW>200, aerosol)

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.



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



Noromycin 300

Safety Data Sheet

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

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, CO<sub>2</sub>). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Ethanolamine (141-43-5)	
LD50 Oral Rat	1720 mg/kg
LD50 Dermal Rabbit	1025 mg/kg
ATE (Vapors)	11.00 mg/l/4h
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 ml/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

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: Ingestion is likely to be harmful or have adverse effects.

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

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ethanolamine (141-43-5)	
LCS0 Fish 1	227 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	3684 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
ErC50 (Algae)	2.5 mg/l

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

Ethanolamine (141-43-5)	
Log Pow	-1.91 (at 25 °C)



Noromycin 300

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

- 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

Noromycin 300	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard
Magnesium oxide (MgO) (1309-48-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Ethanolamine (141-43-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Polyethylene glycol (25322-68-3)	
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	
Ethanolamine (141-43-5)	
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 : 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 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation:vapor)	Acute toxicity (inhalation:vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1B	Skin corrosion/irritation Category 1B
STOT SE 3	Specific target organ toxicity (single exposure) Category 3

# Noromycin 300

## Safety Data Sheet

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

H227	Combustible liquid
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H401	Toxic to aquatic life
H412	Harmful to aquatic life with long lasting effects

*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)