

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

Version: 1.0

SECTION 1: IDENTIFICATION

Product Identifier Product Form: Mixture

Product Name: Noromectin Injection For Cattle and Swine

Product Code: ANADA 200-437

1.2. Intended Use of the Product

Use of the Substance/Mixture: Noromectin® (ivermectin) Injection is an injectable parasiticide for cattle and swine, that effectively treats and controls the following internal and external parasites that may impair the health of cattle and swine: gastrointestinal roundworms (including inhibited Ostertagia ostertagi in cattle), lungworms, grubs, sucking lice, and mange mites of cattle; and gastrointestinal roundworms, lungworms, lice, and mange mites of swine.

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

H302
H319
H361
H370
H372
H402
H412

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) : H302 - Harmful if swallowed.

H319 - Causes serious eye irritation.

H361 - Suspected of damaging fertility or the unborn child.

H370 - Causes damage to organs.

H372 - Causes damage to organs through prolonged or repeated exposure.

H402 - Harmful to aquatic life.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P273 - Avoid release to the environment.

P280 - Wear protective gloves, protective clothing, and eye protection. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell. P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

1/6 06/16/2016 EN (English US)

Safety Data Sheet

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

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

P307+P311 - If exposed: Call a poison center/doctor.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P314 - Get medical advice/attention if you feel unwell.

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

P330 - Rinse mouth.

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
1,2-Propylene glycol	(CAS No) 57-55-6	Proprietary	Not classified
1,3-Dioxolan-4-ylmethanol	(CAS No) 5464-28-8	Proprietary	Eye Irrit. 2A, H319
Ivermectin	(CAS No) 70288-86-7	Proprietary	Acute Tox. 2 (Oral), H300 Acute Tox. 3 (Dermal), H311 Repr. 2, H361 STOT SE 1, H370 STOT RE 1, H372 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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: Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. Causes damage to organs. Causes damage to organs through prolonged or repeated exposure. 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: Causes skin irritation. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

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. Causes damage to organs.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

06/16/2016 EN (English US) 2/6

Safety Data Sheet

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

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.

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. 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.

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

Storage Temperature: 30 °C Max

7.3. Specific End Use(s)

Noromectin® (ivermectin) Injection is an injectable parasiticide for cattle and swine, that effectively treats and controls the following internal and external parasites that may impair the health of cattle and swine: gastrointestinal roundworms (including inhibited Ostertagia ostertagi in cattle), lungworms, grubs, sucking lice, and mange mites of cattle; and gastrointestinal roundworms, lungworms, lice, and mange mites of swine.

06/16/2016 EN (English US) 3/6

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

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).

1,2-Propylen	e glycol (57-55-6)	
USA AIHA	WEEL TWA (mg/m³)	10 mg/m ³

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

Hand Protection Eve Protection

Skin and Body Protection

Respiratory Protection

: Chemically resistant materials and fabrics.

: Wear chemically resistant protective gloves.

: Chemical safety goggles.

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

: 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

Information on Basic Physical and Chemical Properties 9.1.

Physical State Appearance : Clear solution No data available Odor **Odor Threshold** : No data available : No data available pН : No data available **Evaporation Rate Melting Point** : No data available **Freezing Point** No data available **Boiling Point** : No data available : No data available Flash Point **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 : No data available Solubility **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

- Reactivity: Hazardous reactions will not occur under normal conditions. 10.1.
- Chemical Stability: Stable at standard temperature and pressure. 10.2.
- 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.
- Hazardous Decomposition Products: Carbon oxides (CO, CO₂). Nitrogen oxides. 10.6.

06/16/2016 4/6 EN (English US)

Safety Data Sheet

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

Noromectin Injection For Cattle and Swine	
ATE (Oral)	1,000.00 mg/kg body weight
1,2-Propylene glycol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg
Ivermectin (70288-86-7)	
LD50 Oral Rat	10 mg/kg
ATE (Dermal)	300.00 mg/kg body weight

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):** Causes damage to organs.

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: Causes skin irritation. Symptoms may include: Redness, pain, swelling, itching, burning,

dryness, and dermatitis.

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. Causes damage to organs.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or

repeated exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

1,2-Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

1,2-Propylene glycol (57-55-6)	
BCF Fish 1	<1
Log Pow	-0.92

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

Sewage Disposal Recommendations: This material is hazardous to the aquatic environment. Keep out of sewers and waterways. **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.

06/16/2016 EN (English US) 5/6

Safety Data Sheet

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

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

Noromectin Injection For Cattle and Swine		
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard	
	Delayed (chronic) health hazard	
1,2-Propylene glycol (57-55-6)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory		
EPA TSCA Regulatory Flag	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	

15.2. US State Regulations

1,2-Propylene glycol (57-55-6)

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. 2 (Oral)	Acute toxicity (oral) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 2	Reproductive toxicity Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
H300	Fatal if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child
H370	Causes damage to organs
H372	Causes damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
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)

06/16/2016 EN (English US) 6/6