

SAFETY DATA SHEETS

This SDS packet was issued with item:

078913978

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

078913977 078913979 078917135 078917167 078917193 078949398 078949399

According to EC Regulation 1907/2006 (REACH)



MATERIAL SAFETY DATA SHEET

NOROCILLIN INJECTION

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

Product Name	Norocillin 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	:	Penicillins and cephalosporins may cause hypersensitivity following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this product with great care to avoid exposure taking all recommended precautions. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficult breathing are more serious symptoms and require urgent medical attention.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation	:	Preparation
Active Ingredients	:	Penicillin G Procaine
Description	:	Antibiotic
Chemical Family	:	Penicillins

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 vapors.
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 vapors 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, between 2° and 8°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

Penicillin G Procaine

Not Established

For pure penicillin G procaine :

LD50 (Oral, mouse) 2300 mg/kg

LD50 (Oral, rat) > 5000 mg/kg

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

Form	:	Suspension
Color	:	White to off-white
Odor	:	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 Norocillin Injection may cause irritation and/or drying and cracking of the skin.
Inhalation	:	None known.
Ingestion	:	Oral toxicity of the Norocillin Injection 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 Norocillin 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

For Animal Treatment Only

NADA 65-010, approved by FDA

Revision Date : 22/11/10
Revision No : 06

Printing Date : 22/11/2010

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: Norocillin Injection

Product Code: NADA 065-010

1.2. Intended Use of the Product

Use of the Substance/Mixture: Norocillin is indicated for treatment of bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* in cattle and sheep, erysipelas caused by *Erysipelothrix rhusiopathiae* in swine, and strangles caused by *Streptococcus equi* in horses.

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

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.
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.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
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

Norocillin Injection

Safety Data Sheet

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

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]- [2S-(2.alpha., 5.alpha.,6.beta.)]-, monopotassium salt	(CAS No) 113-98-4	Proprietary	Resp. Sens. 1, H334 Skin Sens. 1, H317
Benzoic acid, 4-amino-, 2-(diethylamino)ethyl ester, monohydrochloride	(CAS No) 51-05-8	Proprietary	Acute Tox. 3 (Oral), H301 Skin Sens. 1, H317

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: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. 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: May cause eye irritation.

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).

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. Hydrogen sulfide.

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.

Norocillin Injection

Safety Data Sheet

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

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.

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: 8 °C Max

7.3. Specific End Use(s)

Norocillin is indicated for treatment of bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* in cattle and sheep, erysipelas caused by *Erysipelothrix rhusiopathiae* in swine, and strangles caused by *Streptococcus equi* in horses.

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).

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 goggles or safety glasses.

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

: White solution

Odor

: No data available

Odor Threshold

: No data available

Norocillin Injection

Safety Data Sheet

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

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:** Thermal decomposition generates : Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen sulfide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Benzoic acid, 4-amino-, 2-(diethylamino)ethyl ester, monohydrochloride (51-05-8)	
LD50 Oral Rat	200 mg/kg
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]- [2S-(2.alpha.,5.alpha.,6.beta.)]-, monopotassium salt (113-98-4)	
LD50 Oral Rat	8900 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

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: May cause eye irritation.

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

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]- [2S-(2.alpha.,5.alpha.,6.beta.)]-, monopotassium salt (113-98-4)
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Norocillin Injection

Safety Data Sheet

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

LC50 Fish 1	> 500 mg/l (Exposure time: 96 h - Species: Leuciscus idus melanotus [static])
EC50 Daphnia 1	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]- [2S-(2.alpha.,5.alpha.,6.beta.)]-, monopotassium salt (113-98-4)	
Log Pow	1.83

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

Norocillin Injection	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Benzoic acid, 4-amino-, 2-(diethylamino)ethyl ester, monohydrochloride (51-05-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]- [2S-(2.alpha.,5.alpha.,6.beta.)]-, monopotassium salt (113-98-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations Neither this product nor its chemical components appear on any US state lists.

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. 3 (Oral)	Acute toxicity (oral) Category 3
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Sens. 1	Skin sensitization Category 1
H301	Toxic if swallowed
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

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)