

SAFETY DATA SHEETS

This SDS packet was issued with item:

078394418

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

078912840



MATERIAL SAFETY DATA SHEET

Revision date: 04-Dec-2008

Version: 1.0

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Albadry Plus (US)

Trade Name:	ALBADRY PLUS
Chemical Family:	Mixture
Intended Use:	Veterinary product used for subclinical mastitis in dry cows only

2. HAZARDS IDENTIFICATION

Appearance: Clear, pale yellow, oily liquid
Signal Word: WARNING

Statement of Hazard: May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

Additional Hazard Information:

Short Term: May be harmful if swallowed. May cause skin irritation. (based on components) .

Long Term: May cause effects on blood and blood forming organs, liver.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including skin rash, loss of hair, blood system changes, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis), changes in liver function, effects on gastrointestinal system, nausea, vomiting, diarrhea. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

EU Indication of danger: Harmful
Irritant

EU Hazard Symbols:

Xn



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

Australian Hazard Classification
(NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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Material Name: Albadry Plus (US)
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2. HAZARDS IDENTIFICATION

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Novobiocin Sodium	1476-53-5	216-023-6	Xi;R36-43	5
Chlorobutanol	57-15-8	200-317-6	Xn;R22	0.05
Procaine Penicillin G monohydrate	6130-64-9	Not listed	Xn;R42/43	2

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Aluminum monostearate	7047-84-9	230-325-5	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

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6. ACCIDENTAL RELEASE MEASURES

- Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

- General Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
- Storage Conditions:** Store at controlled room temperature. Keep out of reach of children.
- Storage Temperature:** 20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Novobiocin Sodium

Pfizer OEL TWA-8 Hr: 250 µg/m³, Sensitizer

Aluminum monostearate

ACGIH OELs - Notice of Intended Changes	Listed
Lithuania OEL - TWA	Listed
Sweden OEL - TWAs	= 5 mg/m³ LLV

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Procaine Penicillin G monohydrate

Pfizer Occupational Exposure Band (OEB): OEB 2 - Sensitizer (control exposure to the range of >100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

- Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
- Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.
- Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
- Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
- Eyes:** Wear safety glasses or goggles if eye contact is possible.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Oil Suspension	Color:	Light yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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Material Name: Albadry Plus (US)
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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Novobiocin Sodium

Rat Oral LD 50 3200 mg/kg
Rat Intravenous LD 50 360mg/kg
Rat Intraperitoneal LD 50 370mg/kg
Mouse Oral LD 50 962mg/kg
Mouse Intraperitoneal LD 50 225mg/kg

Chlorobutanol

Rat Oral LD50 510 mg/kg

Procaine Penicillin G monohydrate

Mouse Oral LD50 > 2000 mg/kg
Rat Intravenous LD50 97mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Novobiocin Sodium

Eye Irritation Rabbit Moderate

Chlorobutanol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Novobiocin Sodium

Embryo / Fetal Development Rat Oral 40 mg/kg/day NOAEL Not teratogenic
Reproductive & Fertility Rat Oral 40 mg/kg/day NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Chlorobutanol

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Positive
In Vitro Micronucleus Mouse Bone Marrow Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
Irritant

EU Risk Phrases:
R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Novobiocin Sodium	
Australia (AICS):	Present
EU EINECS/ELINCS List	216-023-6

Aluminum monostearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	230-325-5

Chlorobutanol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 3
	200-317-6

Procaine Penicillin G monohydrate	
Australia (AICS):	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET



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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Penicillin G Procaine and Novobiocin Sodium Suspension

Trade Name: ALBADRY PLUS (R)

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used for subclinical mastitis in dry cows only

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPRecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear, pale yellow, oily liquid

Classification of the Substance or Mixture

Skin Corrosion/Irritation: Category 2
Serious Eye Damage/Eye Irritation: Category 2A
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Harmful
Irritant

EU Symbol: Xn

EU Risk Phrases:
R38 - Irritating to skin.
R42/43 - May cause sensitization by inhalation and skin contact.

Label Elements

Signal Word: Danger

Hazard Statements:
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

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Material Name: Penicillin G Procaine and Novobiocin Sodium
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Precautionary Statements:

P285 - In case of inadequate ventilation wear respiratory protection
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P272 - Contaminated work clothing should not be allowed out of the workplace
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P363 - Wash contaminated clothing before reuse



Other Hazards

Long Term:

Known Clinical Effects:

May cause effects on blood and blood forming organs, liver.
Clinical use of this drug has caused skin rash, loss of hair, blood system changes, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis), changes in liver function
Clinical use has caused effects on the gastrointestinal system, including: nausea, vomiting, diarrhea. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Peanut Oil	8002-03-7	232-296-4	Not Listed	Skin Irrit. 2 (H315)	*
Procaine Penicillin G monohydrate	6130-64-9	Not Listed	Xn;R42/43	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	2

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Material Name: Penicillin G Procaine and Novobiocin Sodium
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Novobiocin Sodium	1476-53-5	216-023-6	Xi;R36 Xi;43	Eye Irrit. 2A (H319) Skin Sens. 1 (H317)	5
Penicillin G procaine	54-35-3	200-205-7	Xn;R42/43	Resp. Sens. 1,H334; Skin Sens. 1,H317	0

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: People allergic to penicillins may exhibit cross reaction sensitivity.

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: The viruses contained in this vaccine are generally not considered to cause disease in humans.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

SAFETY DATA SHEET

Material Name: Penicillin G Procaine and Novobiocin Sodium
Suspension
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Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store in a cool, dry place away from light. Keep out of reach of children.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Novobiocin Sodium

Zoetis OEL TWA 8-hr

250µg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Rubber gloves

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Oil Suspension
Odor: No data available.
Molecular Formula: Mixture

Color: Light yellow
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Novobiocin Sodium

Predicted N/A Log P 0.78

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition No data available

Products:

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Novobiocin Sodium

Rat Oral LD 50 3200 mg/kg

Rat Para-periosteal LD 50 360mg/kg

Rat Intraperitoneal LD 50 370mg/kg

Mouse Oral LD 50 962mg/kg

Mouse Intraperitoneal LD 50 225mg/kg

Procaine Penicillin G monohydrate

Mouse Oral LD50 > 2000 mg/kg

Rat Para-periosteal LD50 97 mg/kg

Penicillin G procaine

PENICILLIN G PROCAINE AND NOVOBIOCIN SODIUM

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11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 > 2000 mg/kg

Rat Oral LD50 > 2000mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Novobiocin Sodium

Eye Irritation Rabbit Moderate

Peanut Oil

Skin Irritation Rabbit Moderate

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Novobiocin Sodium

Embryo / Fetal Development Rat Oral 40 mg/kg/day NOAEL Not teratogenic

Reproductive & Fertility Rat Oral 40 mg/kg/day NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Peanut Oil

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Novobiocin Sodium

Predicted N/A Log P 0.78

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, and Subdivision B.



Peanut Oil

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-296-4

Procaine Penicillin G monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Novobiocin Sodium

CERCLA/SARA 313 Emission reporting	Not Listed
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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	216-023-6

Penicillin G procaine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-205-7

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Xn - Harmful

R38 - Irritating to skin.
R42 - May cause sensitization by inhalation.
R43 - May cause sensitization by skin contact.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET



1. Identification

Product identifier	Penicillin G Procaine and Novobiocin Sodium Suspension
Other means of identification	
Synonyms	Novodry® Plus * ALBADRY PLUS® * NOVODRY PLUS * Albadry Plus Suspension * Novodry Plus Suspension
Recommended use	Veterinary product for the treatment of mastitis in dry cattle
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 2
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Causes skin irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statement	
Prevention	Avoid breathing mist or vapor. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. Take off contaminated clothing and wash before reuse.
Storage	Store away from incompatible materials.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Peanut Oil		8002-03-7	93
Novobiocin Sodium		1476-53-5	5
Procaine Penicillin G monohydrate		6130-64-9	2

4. First-aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. If breathing is difficult, trained personnel should give oxygen.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	May cause eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty in breathing.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.
General information	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Ventilate closed spaces before entering them. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Ensure adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Avoid release to the environment. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Use only with adequate ventilation. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Avoid accidental injection. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. @ 15-30°C (59-86°F). Do not allow material to freeze. Keep away from food, drink and animal feedings. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis**Components****Type****Value**

Novobiocin Sodium (CAS 1476-53-5)

TWA

250 µg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**

Peanut Oil (CAS 8002-03-7)

PEL

5 mg/m³
15 mg/m³

Respirable fraction.
Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value****Form**

Peanut Oil (CAS 8002-03-7)

TWA

5 mg/m³
10 mg/m³

Respirable.
Mist.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

OEL Additional Information: Sensitizer

Control banding approach

Procaine Penicillin G Monohydrate: Zoetis OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits or within the OEB range.

Individual protection measures, such as personal protective equipment**Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

Skin protection**Hand protection**

Wear appropriate chemical resistant gloves. Impervious gloves.

Other

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection.
Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance	Oily. Suspension.
Physical state	Liquid.
Form	Liquid.
Color	Light yellow.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.

Skin contact Causes skin irritation. May cause an allergic skin reaction.
Peanut Oil
Species: Rabbit
Severity: Moderate

Eye contact Direct contact with eyes may cause temporary irritation.
Novobiocin Sodium
Species: Rabbit
Severity: Moderate

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics May cause eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty in breathing.

Information on toxicological effects

Acute toxicity Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe.

Components	Species	Test Results
Novobiocin Sodium (CAS 1476-53-5)		
<u>Acute</u>		
Intraperitoneal		
LD50	Mouse	225 mg/kg
	Rat	370 mg/kg
Oral		
LD50	Mouse	962 mg/kg
	Rat	3200 mg/kg
Other		
LD50	Rat	360 mg/kg (Para-periosteal)
Procaine Penicillin G monohydrate (CAS 6130-64-9)		
<u>Acute</u>		
Oral		
LD50	Mouse	> 2000 mg/kg
Other		
LD50	Rat	97 mg/kg (Para-periosteal)
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Novobiocin Sodium	Species: Rabbit	Severity: Moderate

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization May cause an allergic skin reaction.

Skin sensitization
Novobiocin Sodium

Severity: Sensitizer

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
Peanut Oil

Bacterial Mutagenicity (Ames)
Result: Negative
Species: Salmonella

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects
Novobiocin Sodium

40 mg/kg/day Embryo / Fetal Development, Not teratogenic
Result: NOAEL
Species: Rat
Organ: Oral

Reproductivity
Novobiocin Sodium

40 mg/kg/day Reproductive & Fertility, No effects at maximum dose
Result: NOAEL
Species: Rat
Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible. This product may affect blood and blood forming organs and Liver. through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Clinical use of this drug has caused skin rash, loss of hair, blood system changes, liver effects, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis).

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 12-09-2013**Revision date** 05-22-2017**Version #** 04**Disclaimer**

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information

This document has undergone significant changes and should be reviewed in its entirety.

1. Identification

Product identifier	Penicillin G Procaine and Novobiocin Sodium Suspension
Other means of identification	
Synonyms	Novodry® Plus * ALBADRY PLUS® * NOVODRY PLUS * Albadry Plus Suspension * Novodry Plus Suspension
Recommended use	Veterinary product for the treatment of mastitis in dry cattle
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 2
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Causes skin irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statement	
Prevention	Avoid breathing mist or vapor. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. Take off contaminated clothing and wash before reuse.
Storage	Store away from incompatible materials.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Peanut Oil		8002-03-7	93
Novobiocin Sodium		1476-53-5	5
Procaine Penicillin G monohydrate		6130-64-9	2

4. First-aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. If breathing is difficult, trained personnel should give oxygen.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	May cause eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty in breathing.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.
General information	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Ventilate closed spaces before entering them. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Ensure adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Avoid release to the environment. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Use only with adequate ventilation. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Avoid accidental injection. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. @ 15-30°C (59-86°F). Do not allow material to freeze. Keep away from food, drink and animal feedings. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis**Components****Type****Value**

Novobiocin Sodium (CAS 1476-53-5)

TWA

250 µg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**

Peanut Oil (CAS 8002-03-7)

PEL

5 mg/m³
15 mg/m³

Respirable fraction.
Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value****Form**

Peanut Oil (CAS 8002-03-7)

TWA

5 mg/m³
10 mg/m³

Respirable.
Mist.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

OEL Additional Information: Sensitizer

Control banding approach

Procaine Penicillin G Monohydrate: Zoetis OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits or within the OEB range.

Individual protection measures, such as personal protective equipment**Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

Skin protection**Hand protection**

Wear appropriate chemical resistant gloves. Impervious gloves.

Other

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection.
Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance	Oily. Suspension.
Physical state	Liquid.
Form	Liquid.
Color	Light yellow.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.

Skin contact Causes skin irritation. May cause an allergic skin reaction.
Peanut Oil
Species: Rabbit
Severity: Moderate

Eye contact Direct contact with eyes may cause temporary irritation.
Novobiocin Sodium
Species: Rabbit
Severity: Moderate

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics May cause eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty in breathing.

Information on toxicological effects

Acute toxicity Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe.

Components	Species	Test Results
Novobiocin Sodium (CAS 1476-53-5)		
<u>Acute</u>		
Intraperitoneal		
LD50	Mouse	225 mg/kg
	Rat	370 mg/kg
Oral		
LD50	Mouse	962 mg/kg
	Rat	3200 mg/kg
Other		
LD50	Rat	360 mg/kg (Para-periosteal)
Procaine Penicillin G monohydrate (CAS 6130-64-9)		
<u>Acute</u>		
Oral		
LD50	Mouse	> 2000 mg/kg
Other		
LD50	Rat	97 mg/kg (Para-periosteal)
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Novobiocin Sodium	Species: Rabbit	Severity: Moderate

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization May cause an allergic skin reaction.

Skin sensitization
Novobiocin Sodium

Severity: Sensitizer

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
Peanut Oil

Bacterial Mutagenicity (Ames)
Result: Negative
Species: Salmonella

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects
Novobiocin Sodium

40 mg/kg/day Embryo / Fetal Development, Not teratogenic
Result: NOAEL
Species: Rat
Organ: Oral

Reproductivity
Novobiocin Sodium

40 mg/kg/day Reproductive & Fertility, No effects at maximum dose
Result: NOAEL
Species: Rat
Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible. This product may affect blood and blood forming organs and Liver. through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Clinical use of this drug has caused skin rash, loss of hair, blood system changes, liver effects, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis).

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 12-09-2013**Revision date** 05-22-2017**Version #** 04**Disclaimer**

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information

This document has undergone significant changes and should be reviewed in its entirety.