

SAFETY DATA SHEET



Revision date: 17-Jun-2014

Version: 2.2

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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®, NOVODRY PLUS®
Synonyms: Albadry Plus Suspension; Novodry Plus Suspension
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
Restrictions on Use: Not for human use

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: VMIPSrecords@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
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: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction

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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 + P340 - IF INHALED: Remove victim 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
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P362 - Take off contaminated clothing and wash before reuse
- P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term: May cause eye irritation
Long Term: May cause effects on blood and blood forming organs, liver.
Known Clinical Effects: 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):

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	Xi; R38	Skin Irrit. 2 (H315)	93
Novobiocin Sodium	1476-53-5	216-023-6	Xi;R36 Xi;43	Eye Irrit. 2A (H319) Skin Sens. 1(H317)	5
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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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: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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: None

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.

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.

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7. HANDLING AND STORAGE

Precautions for Safe Handling

Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Avoid accidental injection. Wash thoroughly after handling. When handling, use proper personal protective equipment as specified in Section 8. Prevent environmental releases. 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.

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): Veterinary product for the treatment of subclinical mastitis in dry cows only

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Novobiocin Sodium

Zoetis OEL TWA 8-hr

250 µg/m³, Sensitizer

Procaine Penicillin G monohydrate

Zoetis OEB

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

Exposure Controls

Engineering Controls:

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.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Wear impervious gloves if skin contact is possible.

Eyes:

Safety glasses or goggles

Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

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. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Oil Suspension

Color:

Light yellow

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available.

Melting/Freezing Point (°C):

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.

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 Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

Procaine Penicillin G monohydrate

Mouse Oral LD50 > 2000 mg/kg

Rat Para-periosteal LD50 97 mg/kg

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

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.

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11. TOXICOLOGICAL INFORMATION

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

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.

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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.

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.



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

Novobiocin Sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	216-023-6

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

16. OTHER INFORMATION

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

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Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Xn - Harmful
Xi - Irritant

R38 - Irritating to skin.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R42/43 - May cause sensitization by inhalation and 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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet