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IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Penicillin G Procaine and Novobiocin Sodium Suspension

Trade Name: ALBADRY PLUS (R)
Chemical Family: Not determined

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Novobiocin Sodium	1476-53-5	216-023-6	5
Procaine Penicillin G monohydrate	6130-64-9	Not listed	2
Peanut Oil	8002-03-7	232-296-4	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear, pale yellow, oily liquid

Signal Word: WARNING

Statement of Hazard: Causes skin irritation.

Causes eye irritation.

May cause allergic skin reaction.

May cause allergic respiratory reaction

Additional Hazard Information:

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.

EU Indication of danger: Harmful

Irritant

EU Hazard Symbols:

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EU Risk Phrases:

R38 - Irritating to skin.

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

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

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workplace.

4. 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.

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

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

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

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Novobiocin Sodium

Pfizer OEL TWA-8 Hr: 0.25 mg/m³

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

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

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exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:Oil SuspensionColor:Light yellowMolecular Formula:MixtureMolecular 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.

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 50 360 mg/kg
Rat Intraperitoneal LD 50 370 mg/kg

Mouse Oral LD 50 962 mg/kg

Mouse Intraperitoneal LD 50 225 mg/kg

Procaine Penicillin G monohydrate

Mouse Oral LD 50 > 2 Rat Intravenous LD 50 = 97

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Penicillin G procaine

Mouse Oral LD50 > 2000 Rat Oral LD50 > 2000

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.

<u>Irritation / Sensitization: (Study Type, Species, Severity)</u>

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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:The material should be disposed of by incineration in a chemical incinerator in compliance with

national and regional requirements.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

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EU Labeling: Xn
EU Indication of danger: Harmful
Irritant

EU Risk Phrases:

R38 - Irritating to skin.

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

Causes skin irritation.
Causes eye irritation.
May cause allergic skin reaction.

May cause allergic respiratory reaction

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Novobiocin Sodium

EU EINECS List 216-023-6

Peanut Oil

EU EINECS List 232-296-4
Inventory - United States TSCA - Sect. 8(b) Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet