

# SAFETY DATA SHEET



Revision date: 13-Mar-2014

Version: 3.0

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

### Product Identifier

**Material Name:** Orbenin Dry Cow; Orbenin Extra Dry Cow Intramammary Suspension

**Trade Name:** Orbenin™  
**Chemical Family:** Penicillin

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

**Intended Use:** Veterinary antibiotic agent

### 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:** Off-white suspension

### Classification of the Substance or Mixture

Aspiration Toxicity: Category 1  
Respiratory Sensitization: Category 1  
Skin Sensitization: Category 1

### EU Classification:

EU Indication of danger: Harmful

EU Symbol: Xn  
EU Risk Phrases:

R65 - Harmful: may cause lung damage if swallowed.  
R42/43 - May cause sensitization by inhalation and skin contact.

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H304 - May be fatal if swallowed and enters airways  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction

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**Precautionary Statements:**

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P284 - Wear respiratory protection
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
- P331 - Do NOT induce vomiting
- 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
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**  
**Short Term:**

May cause allergic reaction in penicillin-sensitive individuals. Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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	EU Classification	GHS Classification	%
Stearic acid	57-11-4	200-313-4	Not Listed	Not Listed	*
Aluminum stearate	637-12-7	211-279-5	Not Listed	Not Listed	*
Liquid Paraffin	92062-35-6	295-550-3	Xn; R65	Asp. Tox. 1 (H304)	75.7
Cloxacillin benzathine	23736-58-5	245-855-2	Xn; R42/43	Resp. Sens. Cat. 1 (H334) Skin Sens. Cat. 1 (H317)	25

**Additional Information:**

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

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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:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.
- Ingestion:** In the event of swallowing this material, seek immediate medical attention. DO NOT INDUCE VOMITING. Never give anything by mouth to an unconscious person.
- Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

#### 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:** 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:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

### 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

When handling, use appropriate personal protective equipment (see Section 8). Use appropriate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist. Wash thoroughly after handling. Keep away from heat, sparks, and flame.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store in a cool, dry, well-ventilated area.

**Storage Temperature:** Store below 25°C

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

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Aluminum stearate

**ACGIH Threshold Limit Value (TWA)** 1 mg/m<sup>3</sup>

**Lithuania OEL - TWA** 5 mg/m<sup>3</sup>

**Sweden OEL - TWAs** 5 mg/m<sup>3</sup>

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.

#### Cloxacillin benzathine

##### Zoetis OEB

OEB 2 - Sensitizer (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Exposure Controls

##### 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.

##### 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 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:

Suspension

#### Odor:

No data available.

#### Molecular Formula:

Mixture

#### Color:

White to off-white

#### Odor Threshold:

No data available.

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available  
pH: No data available.  
Melting/Freezing Point (°C): No data available  
Boiling Point (°C): No data available.  
Partition Coefficient: (Method, pH, Endpoint, Value)  
No data available  
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): Expected to be >55°C  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

### 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: High temperatures Fine particles (such as 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: The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the formulation have not been investigated.

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

##### Stearic acid

Rat Oral LD50 > 4640 mg/kg  
Rabbit Dermal LD50 > 5000mg/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)

##### Stearic acid

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Mild

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### 11. TOXICOLOGICAL INFORMATION

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **Stearic acid**

30 Week(s) Rat Oral 300 ppm LOEL Adipose tissue

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

##### **Stearic acid**

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Unscheduled DNA Synthesis *E. coli* Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Stearic acid**

26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOEL Not carcinogenic  
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOEL Tumors

#### Carcinogen Status:

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

### 12. ECOLOGICAL INFORMATION

#### **Environmental Overview:**

Penicillins are susceptible to degradation by a number of microorganisms found in wastewater treatment plants and the general environment. Resulting degradation products are readily mineralized by environmental microorganisms.

#### **Toxicity:**

No data available

#### **Persistence and Degradability:**

No data available

#### **Bio-accumulative Potential:**

No data available

#### **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, 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.



#### Stearic acid

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	200-313-4

#### Aluminum stearate

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	211-279-5

#### Liquid Paraffin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	295-550-3

#### Cloxacillin benzathine

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

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List

245-855-2

### 16. OTHER INFORMATION

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

H304 - May be fatal if swallowed and enters airways

H317 - May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Xn - Harmful

R65 - Harmful: may cause lung damage if swallowed.

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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. 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**