

# SAFETY DATA SHEET



Revision date: 30-Apr-2015

Version: 2.5

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

### Product Identifier

**Material Name:** OrbeSeal®

**Trade Name:** Teat Seal  
**Synonyms:** OrbeSeal, Teatseal  
**Chemical Family:** Mixture

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

**Intended Use:** Veterinary product used as Non-antibiotic intramammary dry cow treatment  
**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 and Drug 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:** Grayish white viscous oily paste with a paraffin odor in a disposable syringe

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4

#### EU Classification:

**EU Symbol:** Harmful; (Xn)  
**EU Risk Phrases:** R22 - Harmful if swallowed.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H302 - Harmful if swallowed

**Precautionary Statements:** P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P501 - Dispose of contents/container in accordance with all local and national regulations

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### Other Hazards

#### Short Term:

May cause skin irritation. Signs and symptoms might include skin rash, itching, redness or swelling.

#### Long Term:

May cause damage to liver and kidneys (based on components)

### 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	%
Bismuth subnitrate	1304-85-4	215-136-8	Xn; R22	Acute Tox. 4 (H302)	65
Liquid paraffin	92062-35-6	295-550-3	Not Listed	Not Listed	< 30
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	Not Listed	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Aluminum di-/tristearate (ALUGEL 30 HEP)	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

### Additional Information:

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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. If irritation occurs or persists, get medical attention.

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**Ingestion:** Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get 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:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Carbon dioxide, dry powder, or foam.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide, and oxides of nitrogen

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

### Advice for Fire-Fighters

Evacuate area and fight fire from a safe distance. Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

**Additional Information:** This product contains an oxidizer and may support combustion. Paraffin is combustible.

## 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.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Use with adequate ventilation. Keep away from heat, sparks, and flame. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store in a cool, dry, well-ventilated area. Protect from light. Keep away from heat, sparks, and flames. Keep container tightly closed when not in use.

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**Storage Temperature:** Store as directed by product packaging.  
**Incompatible Materials:** Strong oxidizing agents and strong acids , organic materials , combustible materials  
**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.

#### Colloidal silicon dioxide

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Switzerland OEL -TWAs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

#### 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 aerosols.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Chemical protective gloves

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Wear protective clothing when working with large quantities.

**Respiratory protection:** Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Smooth Oily Paste	<b>Color:</b>	Grayish White
<b>Odor:</b>	Paraffin odor	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Insoluble: Water (based on components)		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	260 based on highest component melting point (Bismuth subnitrate)		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
	No data available		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**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:** 4.93 (Bismuth subnitrate)  
**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available  
**Flammability (Solids):** No data available  
**Flash Point (Liquid) (°C):** 179 based on lowest component boiling point (Paraffin)  
**Upper Explosive Limits (Liquid) (% by Vol.):** No data available  
**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:**

Will not occur

**Additional Information:**

There are no data available for this mixture. The information given in this section is for major component(s).

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** Bismuth subnitrate is an oxidizer.

**Conditions to Avoid:** Keep away from heat, spark, flames and all other sources of ignition. Avoid prolonged exposure to higher temperatures and/or direct sunlight.

**Incompatible Materials:** Strong oxidizing agents and strong acids, organic materials, combustible materials

**Hazardous Decomposition Products:** Toxic or corrosive oxides of carbon and nitrogen.

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: skin contact

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

**Bismuth subnitrate**

Mouse Oral Minimum Lethal Dose 1200 mg/kg

**Ingestion Acute Toxicity** Harmful if swallowed.

**Skin Irritation / Sensitization** May cause skin irritation.

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

**Bismuth subnitrate**

3 Day(s) Rabbit Subcutaneous 5 g/kg/day LOAEL Kidney

60-70 Day(s) Rat Oral 5 g/kg/day LOAEL Liver, Kidney,

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### 11. TOXICOLOGICAL INFORMATION

<b>Subchronic Effects</b>	Single or multiple subcutaneous injections of bismuth subnitrate into female mice produced neurological signs including ataxia, tremors, and convulsions. Hydrocephalus and axonal swelling in the spinal cord were the major neuropathological lesions.
<b>Carcinogen Status:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below
<b>Colloidal silicon dioxide IARC:</b>	Group 3 (Not Classifiable)
<b>Product Level Toxicity Data Acute Toxicity Estimate (ATE), dermal</b>	ca. 1851 mg/kg

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	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.

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### 15. REGULATORY INFORMATION

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

##### Canada - WHMIS: Classifications

###### WHMIS hazard class:

Non-controlled

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

##### Bismuth subnitrate

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	215-136-8

##### Liquid paraffin

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

##### Colloidal silicon dioxide

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	231-545-4

##### Aluminum di-/tristearate (ALUGEL 30 HEP)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

#### Data Sources:

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

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**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology 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**