SAFETY DATA SHEET

1. Identification

Product identifier Orbeseal®, Teatseal®
Other means of identification
Synonyms Non-antibiotic sterile intramammary paste
Recommended use of the chemical and restrictions on use
Recommended use Veterinary product used as Non-antibiotic intramammary dry cow treatment
Restrictions on use Not for human use
Details of manufacturer or importer
Company Name (AU) Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW 2138 AUSTRALIA
Tel 1800 814 883
Fax (02) 8876 0444
Email productsupport.au@zoetis.com
Emergency Phone 1800 814 883 (all hours)
Police and Fire Brigade Dial 000
If ineffective Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical
Physical hazards Not classified.
Health hazards Acute toxicity, oral Category 4
Environmental hazards Not classified.
Label elements, including precautionary statements
Hazard symbol(s)
Exclamation mark
Signal word Warning
Hazard statement(s) Harmful if swallowed.
Precautionary statement(s)
Prevention Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
Response IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. Rinse mouth.
Storage Store away from incompatible materials.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards which do not result in classification None known.
Supplemental information This product contains an oxidizer and may support combustion.

3. Composition/information on ingredients

Mixture
Environmental precautions

5. Identity of chemical ingredients

<table>
<thead>
<tr>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth subnitrate</td>
<td>1304-85-4</td>
<td>65</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>&lt;10*</td>
</tr>
<tr>
<td>Liquid paraffin</td>
<td>92062-35-6</td>
<td>20 - 30*</td>
</tr>
</tbody>
</table>

Composition comments

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Description of necessary first aid measures

Inhalation
Move to fresh air. Call a POISON CENTRE or doctor/physician if you feel unwell. For breathing difficulties, oxygen may be necessary.

Skin contact
Wash off with soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

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. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Personal protection for first-aid responders
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. Show this safety data sheet to the doctor in attendance.

Symptoms caused by exposure
Coughing. Dermatitis. May cause skin irritation. Direct contact with eyes may cause temporary irritation. Skin irritation. May cause redness and pain.

Medical attention and special treatment
Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

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
May intensify fire; oxidiser. During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use water spray to cool unopened containers.

Hazchem code
None.

General fire hazards
This product contains an oxidizer and may support combustion. Paraffin is combustible. Assume that this material is capable of sustaining combustion.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel
Keep unnecessary personnel away.

For emergency responders
Use personal protection recommended in Section 8 of the SDS. Ensure adequate ventilation. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ventilate the contaminated area. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Do not breathe mist or vapour.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.
Methods and materials for containment and cleaning up

Ensure adequate ventilation. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Clean surface thoroughly to remove residual contamination.

Small Spills: Absorb in vermiculite, dry sand or earth and place into containers. 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.

7. Handling and storage

Precautions for safe handling

Use with adequate ventilation. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Avoid breathing mist or vapour. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Protect from light. Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat, sparks and open flame. Do not store near combustible materials. Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children.

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

| Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A) |
| --- | --- | --- |
| Components | Type | Value | Form |
| Colloidal silicon dioxide (CAS 7631-86-9) | TWA | 2 mg/m³ | Respirable dust. |
| Liquid paraffin (CAS 92062-35-6) | TWA | 5 mg/m³ | |

| US. ACGIH Threshold Limit Values |
| --- | --- | --- |
| Components | Type | Value | Form |
| Liquid paraffin (CAS 92062-35-6) | TWA | 5 mg/m³ | Inhalable fraction. |

| Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG) |
| --- | --- | --- |
| Components | Type | Value | Form |
| Colloidal silicon dioxide (CAS 7631-86-9) | TWA | 4 mg/m³ | Inhalable fraction. |
| Liquid paraffin (CAS 92062-35-6) | TWA | 5 mg/m³ | Respirable fraction. |

Biological limit values

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

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection

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

Skin protection

Hand protection

Wear appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection
In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

Hygiene measures
Keep away from food and drink. 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.

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid.</td>
</tr>
<tr>
<td>Form</td>
<td>Solid.</td>
</tr>
<tr>
<td>Colour</td>
<td>Grayish White.</td>
</tr>
<tr>
<td>Odour</td>
<td>Paraffin odor.</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>260 °C (500 °F)</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>179.0 °C (354.2 °F) estimated</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td></td>
</tr>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit – upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Other physical and chemical parameters</td>
<td></td>
</tr>
<tr>
<td>Density</td>
<td>4.93 (Bismuth subnitrate)</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive.</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>This product contains an oxidizer and may support combustion.</td>
</tr>
</tbody>
</table>

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. Keep away from heat, spark, open flames and other sources of ignition. Avoid high temperatures. Protect from sunlight.

Incompatible materials

Hazardous decomposition products
Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Nitrogen oxides (NOx). Carbon oxides.

11. Toxicological information

Information on possible routes of exposure
Inhalation
No adverse effects due to inhalation are expected.

Skin contact
No adverse effects due to skin contact are expected. Prolonged skin contact may cause temporary irritation.

Eye contact
Direct contact with eyes may cause temporary irritation.

Ingestion
Harmful if swallowed.

Symptoms related to exposure
Direct contact with eyes may cause temporary irritation. Coughing. May cause skin irritation. Dermatitis. Skin irritation. May cause redness and pain.

Acute toxicity
Harmful if swallowed.

Components

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bismuth subnitrate (CAS 1304-85-4)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td>1200 mg/kg (Minimum Lethal Dose)</td>
</tr>
<tr>
<td><strong>Subacute</strong></td>
<td></td>
</tr>
<tr>
<td>Subcutaneous</td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td>5 g/kg/day, 3 days (Target organ(s): Kidney)</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td>5 g/kg/day, 60 days (Target organ(s): Liver, Kidney)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Colloidal silicon dioxide (CAS 7631-86-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute</strong></td>
</tr>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>LD50</td>
</tr>
<tr>
<td>Rat</td>
</tr>
<tr>
<td>&gt; 22500 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Prolonged skin contact may cause temporary irritation.

Serious eye damage/irritation
Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitisation

Respiratory sensitisation
Not a respiratory sensitizer.

Skin sensitisation
This product is not expected to cause skin sensitisation.

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

Carcinogenicity
Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens
Liquid paraffin (CAS 92062-35-6) A2 Suspected human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity
Colloidal silicon dioxide (CAS 7631-86-9) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity
Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - single exposure
Not classified.

Specific target organ toxicity - repeated exposure
Not classified.

Aspiration hazard
Not an aspiration hazard.
Chronic effects
None expected under normal and foreseeable conditions of use. Repeated absorption may cause disorder of central nervous system, liver, kidneys and blood.

12. Ecological information
Ecotoxicity
Due to partial or complete lack of data the classification for hazardous to the aquatic environment, is not possible. 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 for this product.

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 methods
Avoid release to the environment. 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.

Residual waste
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.

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
ADG
Not regulated as dangerous goods.

RID
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 applicable.

15. Regulatory information
Safety, health and environmental regulations
This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 51357
Poison Schedule (Product) – Schedule 0

Australia Medicines & Poisons Appendix A
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B
Bismuth subnitrate (CAS 1304-85-4)

Australia Medicines & Poisons Appendix D
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E
Liquid paraffin (CAS 92062-35-6)

Australia Medicines & Poisons Appendix F
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H
Poisons schedule number not allocated.
Material name: Orbeseal®, Teatseal®

262-ZA

Australia Medicines & Poisons Appendix I
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5
Liquid paraffin (CAS 92062-35-6)

Australia Medicines & Poisons Schedule 6
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9
Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)
Colloidal silicon dioxide (CAS 7631-86-9) 10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Not listed.

Prohibited Carcinogenic Substances
Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)
Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)
Not listed.

Restricted Carcinogenic Substances
Not regulated.

International regulations

Stockholm Convention
Not applicable.

Rotterdam Convention
Not applicable.

Kyoto Protocol
Not applicable.

Montreal Protocol
Not applicable.

Basel Convention
Not applicable.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Industrial Chemicals (AICIS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>Country(s) or region</td>
<td>Inventory name</td>
<td>On inventory (yes/no)*</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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

**Issue date**
10-November-2016

**Revision date**
29-November-2021

**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.