

Section 1 - Identification of the Material and Supplier

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| | |
|-----------------------------|--|
| Chemical nature: | Blend of ingredients |
| Trade Name: | Orbenin Enduro |
| Product Use: | Treatment of mastitis in cattle in their dry period. Bactericidal with activity against penicillin resistant and sensitive staphylococci, streptococci and <i>Corynebacterium pyogenes</i> and other organisms susceptible to cloxacillin. |
| Creation Date: | July 2006 |
| This version issued: | 22 September 2021 and is valid for 5 years from this date |

Section 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

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

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

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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.

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.

Section 3 - Composition/Information on Ingredients

| Hazardous Ingredients | CAS No | Conc, % | GHS Classification |
|------------------------|------------|---------|---|
| Stearic acid | 57-11-4 | * | Not Listed |
| Aluminum stearate | 637-12-7 | * | Not Listed |
| Liquid Paraffin | 92062-35-6 | >60 | Asp. Tox. 1 (H304) |
| Cloxacillin benzathine | 23736-58-5 | 25 | Resp. Sens. Cat. 1 (H334) Skin Sens. Cat. 1 (H317) |

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

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 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.

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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

Section 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 Formation of toxic gases is possible during heating or fire.

Products:

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.

Section 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.

Section 7 - Handling and Storage

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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

Section 8 - Exposure Controls and Personal Protection
Control Parameters**Aluminum stearate**

ACGIH Threshold Limit Value (TWA) 1 mg/m³

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/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. 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.

Section 9 - Physical and Chemical Properties:
Physical State:

Suspension

Color:

White to off-white

Odor:

No data available

Odor Threshold:

No data available

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| | | | |
|---|----------------------|--------------------------|---------|
| 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 | | |
| 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 | | |

Section 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 |

Section 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.

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Irritation / Sensitization: (Study Type, Species, Severity)

Stearic acid

Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Mild

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.

Section 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

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty syringes by wrapping with paper and putting in garbage. For larger quantities, use a commercial waste disposal service.

Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.

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Not regulated for transport under IATA, ADG or IMDG regulations.

Section 15 - Regulatory Information

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

Poison Schedule: Schedule 4

Stearic acid

Australia (AICS): Present

Aluminum stearate

Australia (AICS): Present

Liquid Paraffin

Australia (AICS): Present

Cloxacillin benzathine

Australia (AICS): Present

Section 16 - Other Information

This MSDS contains only safety-related information. For other data see product literature.

Acronyms:

| | |
|---------------------|---|
| ADG Code | Australian Code for the Transport of Dangerous Goods by Road and Rail, 7th Edition |
| AICS | Australian Inventory of Chemical Substances |
| SWA | Safe Work Australia, formerly ASCC and NOHSC |
| CAS number | Chemical Abstracts Service Registry Number |
| Hazchem Code | Emergency action code of numbers and letters that provide information to emergency services especially firefighters |
| IARC | International Agency for Research on Cancer |
| NOS | Not otherwise specified |
| NTP | National Toxicology Program (USA) |
| R-Phrase | Risk Phrase |
| SUSMP | Standard for the Uniform Scheduling of Medicines & Poisons |
| UN Number | United Nations Number |

This version issued: 22 September 2021 and is valid for 5 years from this date

Supersedes: Revision issued 1 October 2016

Revision History:

| Date of Revision | Reason |
|------------------|--|
| Oct 2015 | Update to Zoetis name and address |
| 15 August 2016 | Update to GHS format. |
| 1 Oct 2016 | Minor corrections and updates including updating disposal instructions. Additional hazard information related to paraffin. |
| 22 Sep 2021 | Periodical revision |

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Issued by: Zoetis Australia Pty Ltd

Phone: 1800 814 883

Poisons Information Centre: 13 11 26 from anywhere in Australia, (0800 764 766 in New Zealand)

Contact Points:

| | |
|--------------------------|--------------|
| Zoetis | 1800 814 883 |
| Police and Fire Brigade: | Dial 000 |

If ineffective:**Dial Poisons Information Centre
(13 11 26 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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End of Safety Data Sheet

MATERIAL SAFETY DATA SHEET