Section 1 - Identification of the Material and Supplier

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Rhodes NSW 2138 AUSTRALIA
Tel: 1800 814 883
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Email: productsupport.au@zoetis.com

Substance: Blend of ingredients. Active ingredients are antibiotics
Trade Name: Mastalone
Product Use: Broad spectrum antibiotic for the treatment of mastitis in lactating cattle
Creation Date: September 2006
This version issued: 22 September 2021 and is valid for 5 years from this date

Section 2 - Hazards Identification

Appearance: Yellow oily suspension

Classification of the Substance or Mixture
GHS – Classification
Skin Corrosion/Irritation: Category 2
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Reproductive Toxicity: Category 1A

Label Elements
Signal Word: Danger
Hazard Statements:
H315 - Causes skin irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H360 - May damage fertility or the unborn child

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P317 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

Short Term:
May produce slight eye irritation. (based on components)

Long Term:
Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects:
Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Photosensitivity has been reported in some individuals taking tetracyclines. Clinical use of this drug has caused liver effects and kidney dysfunction.

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.

Additional Information:
For a more detailed discussion of potential health hazards and toxicity see Section 11.

Section 3 - Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Hazardous Ingredients</th>
<th>CAS No</th>
<th>Conc,%</th>
<th>GHS Classification</th>
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<tbody>
<tr>
<td>Oleandomycin Phosphate</td>
<td>7060-74-4</td>
<td>1.2</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sorbitan monostearate</td>
<td>1338-41-6</td>
<td>*</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>31566-31-1</td>
<td>*</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Peanut Oil</td>
<td>8002-03-7</td>
<td>*</td>
<td>Skin Irrit. 2 (H315)</td>
</tr>
<tr>
<td>Butylated hydroxytoluene</td>
<td>128-37-0</td>
<td>*</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Oxytetracycline hydrochloride</td>
<td>2058-46-0</td>
<td>2.0</td>
<td>Repr. 1A (H360)</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>1.5</td>
<td>Resp. Sens. 1 (H334)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens.1(H317)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repro. 2 (H361)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aq. Acute 3 (H402)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aq. Chronic 3 (H412)</td>
</tr>
</tbody>
</table>

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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

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

Section 5 - Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Keep away from heat, sparks, and flame.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Keep container tightly closed when not in use.

Specific end use(s): No data available

Section 8 - Exposure Controls and Personal Protection

Control Parameters

Butylated hydroxytoluene

Australia TWA 10 mg/m³

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: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9 - Physical and Chemical Properties:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Oily Suspension</th>
<th>Color:</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>
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)
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
Specific Gravity: 0.92–0.95
Viscosity: No data available
Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  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 at ambient temperatures
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  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)
Butylated hydroxytoluene
  Rat Oral LD₅₀ 1700 mg/kg
  Mouse Oral LD₅₀ 650 mg/kg
Glyceryl monostearate
  Mouse IP LD₅₀ 200 mg/kg
Oxytetracycline hydrochloride
Mouse Oral LD₅₀ 6696 mg/kg
Mouse SC LD₅₀ > 600mg/kg
Rat SC LD₅₀ 800mg/kg
Mouse IV LD₅₀ 100mg/kg
Rat IV LD₅₀ 302mg/kg

Neomycin Sulfate
Rat Oral LD₅₀ 2750 mg/kg
Mouse Oral LD₅₀ 2880mg/kg
Mouse Intraperitoneal LD₅₀ 116mg/kg
Rat Subcutaneous LD₅₀ 633mg/kg
Mouse Subcutaneous LD₅₀ 275mg/kg

Oleandomycin Phosphate
Rabbit Dermal LD₅₀ > 2000 mg/kg
Mouse Oral LD₅₀ 4000mg/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)

Peanut Oil
Skin Irritation Rabbit Moderate

Butylated hydroxytoluene
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

Neomycin Sulfate
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Minimal
Skin Sensitization Positive

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

Butylated hydroxytoluene
4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver
4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

Oxytetracycline hydrochloride
13 Week(s) Mouse Oral 3821 mg/kg/day NOAEL None identified
13 Week(s) Rat Oral 3352 mg/kg/day NOAEL Liver
12 Month(s) Dog Oral 125 mg/kg/day NOAEL Male reproductive system
24 Month(s) Dog Oral 250 mg/kg/day NOAEL None identified
14 Day(s) Oral 108 g/kg LOEL Brain

Neomycin Sulfate
6 Week(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Guinea Pig Oral 10 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Dog Subcutaneous 20 mg/kg/day LOAEL Kidney
12 Month(s) Cat Oral 12 mg/kg/day NOAEL Blood forming organs
3 Month(s) Guinea Pig Subcutaneous 10 mg/kg/day LOAEL Kidney

Oleandomycin Phosphate

MATERIAL SAFETY DATA SHEET
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)
Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

**Butylated hydroxytoluene**

Embryo / Fetal Development  
Rat  
Oral  
6 g/kg  
LOEL  
Teratogenic

**Oxytetracycline hydrochloride**

2 Generation Reproductive Toxicity  
Rat  
Oral  
18 mg/kg/day  
NOAEL  
No effects at maximum dose

Embryo / Fetal Development  
Rat  
Oral  
1500 mg/kg/day  
NOAEL  
Maternal Toxicity

Embryo / Fetal Development  
Mouse  
Oral  
2100 mg/kg/day  
NOAEL  
Embryotoxicity

**Neomycin Sulfate**

Reproductive & Fertility  
Mouse  
Oral  
4000 mg/L  
NOAEL  
No effects at maximum dose

2 Generation Reproductive Toxicity  
Rat  
Oral  
25 mg/kg/day  
NOAEL  
Fetotoxicity

Reproductive & Fertility  
Rat  
Oral  
25 mg/kg/day  
NOAEL  
No effects at maximum dose

Prenatal & Postnatal Development  
Rat  
Subcutaneous  
6 mg/kg/day  
LOAEL  
Developmental toxicity

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

**Peanut Oil**

Bacterial Mutagenicity (Ames)  
*Salmonella*  
Negative

**Oxytetracycline hydrochloride**

Bacterial Mutagenicity (Ames)  
*Salmonella*  
Negative

*In Vitro* Chromosome Aberration  
Chinese Hamster Ovary (CHO) cells  
Negative

Sister Chromatid Exchange  
Chinese Hamster Ovary (CHO) cells  
Negative

Micronucleus  
Mouse  
Negative

Mammalian Cell Mutagenicity  
Mouse Lymphoma  
Positive with activation

**Neomycin Sulfate**

Bacterial Mutagenicity (Ames)  
*Salmonella, E. coli*  
Negative

Mammalian Cell Mutagenicity  
Chinese Hamster Ovary (CHO) cells  
Negative

*In Vivo* Cytogenetics  
Mouse  
Negative

*In Vitro* Chromosome Aberration  
Human Lymphocytes  
Positive

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

**Oxytetracycline hydrochloride**

24 Month(s)  
Rat  
Oral, in feed  
150 mg/kg/day  
NOEL  
Not carcinogenic

103 Week(s)  
Mouse  
Oral, in feed  
1372 mg/kg/day  
NOEL  
Not carcinogenic

**Neomycin Sulfate**

2 Year(s)  
Rat  
Oral  
25 mg/kg/day  
NOAEL  
Not carcinogenic

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

**Butylated hydroxytoluene**

IARC:  
Group 3 (Not Classifiable)

Section 12 - Ecological Information

Environmental Overview:  
Environmental properties have not been investigated.
Toxicity:

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Oxytetracycline hydrochloride**
- *Oncorhynchus mykiss* (Rainbow Trout) ASTM EPA LC50 96 Hours > 116 mg/L
- *Daphnia magna* (Water Flea) ASTM EPA EC50 48 Hours > 102 mg/L
- *Lepomis macrochirus* (Bluegill Sunfish) ASTM EPA LC50 96 Hours > 94.9 mg/L
- *Selenastrum capricornutum* (Green Alga) ISO EC50 72 Hours 4.18 mg/L

**Neomycin Sulfate**
- *Daphnia magna* (Water Flea) OECD EC50 48 Hours 68 mg/L
- *Salmo gairdneri* (Trout) OECD NOEC 96 Hours >1000 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

**Neomycin Sulfate**
- Activated sludge OECD EC50 399 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Neomycin Sulfate**
- Predicted 7.4 Log D 1.20

**Mobility in Soil:** No data available

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**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.

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

**Sorbitan monostearate Australia (AICS):** Present

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MATERIAL SAFETY DATA SHEET

Issued by: Zoetis Australia Pty Ltd
Poisons Information Centre: 13 11 26 from anywhere in Australia, (0800 764 766 in New Zealand)
Glyceryl monostearate Australia (AICS): Present

Peanut Oil Australia (AICS): Present

Butylated hydroxytoluene Australia (AICS): Present

Oxytetracycline hydrochloride Australia (AICS): Present

Neomycin Sulfate 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
AICS Australian Inventory of Chemical Substances
ASCC Office of the Australian Safety and Compensation Council
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)
SUSDP Standard for the Uniform Scheduling of Drugs & 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:

<table>
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<tr>
<th>Date of Revision</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2015</td>
<td>Update to Zoetis name and address</td>
</tr>
<tr>
<td>01 Oct 2016</td>
<td>Update to GHS format</td>
</tr>
<tr>
<td>22 Sep 2021</td>
<td>Periodical revision</td>
</tr>
</tbody>
</table>

Contact Points:

Zoetis 1800 814 883 Dial 000

Police and Fire Brigade: 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