Section 1 - Identification of the Material and Supplier

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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:	**1 October 2016** 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
P342 + P311 - 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

Hazardous

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

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:

Physical State:	Oily Suspension	**Color:**	Yellow
Odor:	No data available	**Odor Threshold:**	No data available
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
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 LD_{50} 1700 mg/kg
Mouse Oral LD_{50} 650 mg/kg
Rat Oral LD50 890 mg/kg
Mouse Intraperitoneal LD_{50} 138 mg/kg

Glyceryl monostearate
Mouse IP LD_{50} 200 mg/kg

Oxytetracycline hydrochloride
Mouse Oral LD_{50} 6696 mg/kg
Mouse SC LD_{50} > 600mg/kg
Rat SC LD_{50} 800mg/kg
Mouse IV LD_{50} 100mg/kg
Rat IV LD_{50} 302mg/kg

Neomycin Sulfate
Rat Oral LD_{50} 2750 mg/kg
Mouse Oral LD_{50} 2880mg/kg
Mouse Intraperitoneal LD_{50} 116mg/kg
Rat Subcutaneous LD_{50} 633mg/kg
Mouse Subcutaneous LD_{50} 275mg/kg

Oleandomycin Phosphate
Rabbit Dermal LD_{50} > 2000 mg/kg
Mouse Oral LD_{50} 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

19 Week(s) Rat Inhalation =19 mg/m3 LOAEL Liver, Blood
9 Week(s) Rat Oral = 1800 mg/kg LOAEL Skin

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

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

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: 1 October 2016 and is valid for 5 years from this date
Supersedes: Revision issued October 2015

Revision History:

Date of Revision	Reason
October 2015	Update to Zoetis name and address
01 Oct 2016	Update to GHS format

Contact Points:

Zoetis	**1800 814 883 Dial 000**
Police and Fire Brigade:	

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)

End of Safety Data Sheet