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

Product Identifier
Material Name: Aureomycin® 100G
Trade Name: AUREOMYCIN
Chemical Family: Tetracycline derivative

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Veterinary product used as Antibacterial

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 Control 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

2. HAZARDS IDENTIFICATION

Appearance: Brown solid

Classification of the Substance or Mixture
GHS - Classification
Reproductive Toxicity: Category 1A

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

EU Classification:
EU Indication of danger: Toxic
EU Symbol: T
EU Risk Phrases:
R61 - May cause harm to the unborn child.

Label Elements
Signal Word: Danger
Hazard Statements:
May form combustible dust concentrations in air
H360 - May damage fertility or the unborn child
Precautionary Statements:
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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: Exposure to sunlight following contact may result in skin reactions in rare instances. May be harmful to aquatic organisms.

Long Term: High doses of tetracyclines can cause a liver condition known as fatty liver. Individuals who suffer from high cholesterol, high triglycerides, or have alcoholic liver disease may be more susceptible. May produce kidney toxicity if kidney damage already exists (based on animal data).

Known Clinical Effects: May cause permanent discoloration of teeth if used during tooth development. 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.

Australian Hazard Classification (NOHSC):

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlortetracycline hydrochloride</td>
<td>64-72-2</td>
<td>200-591-7</td>
<td>Repr. Cat.1;R61</td>
<td>Repro Tox 1A (H360)</td>
<td>90-93</td>
</tr>
<tr>
<td>Mineral oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium sulfate, dihydrate</td>
<td>10101-41-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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: 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

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.

Fire / Explosion Hazards: During processing, dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel must wear appropriate protective equipment (see Section 8). Minimize exposure. Avoid dust formation.

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

Measure for Cleaning / Collecting: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Clean spill area thoroughly.
Additional Consideration for Large Spills:
Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. 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
Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid open handling. Minimize dust generation and accumulation. When handling, use appropriate personal protective equipment (see Section 8). 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
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.

Chlortetracycline hydrochloride
Zoetis OEL TWA 8-hr 0.5 mg/m³

Mineral oil
ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
Belgium OEL - TWA 5 mg/m³
Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 5 mg/m³
Denmark OEL - TWA 1 mg/m³
Finland OEL - TWA 5 mg/m³
Greece OEL - TWA 5 mg/m³
Lithuania OEL - TWA 1 mg/m³
Netherlands OEL - TWA 5 mg/m³
Vietnam OEL - TWAs 5 mg/m³
OSHA - Final PELS - TWAs: 5 mg/m³
Poland OEL - TWA 5 mg/m³
Portugal OEL - TWA 5 mg/m³
Romania OEL - TWA 5 mg/m³
Slovakia OEL - TWA 5 ppm
1 mg/m³
5 mg/m³
Spain OEL - TWA 5 mg/m³
Sweden OEL - TWAs 1 mg/m³

Calcium sulfate, dihydrate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Germany (DFG) - MAK 1.5 mg/m³
4 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid

Color: Brown

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

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

10. STABILITY AND REACTIVITY

Reactivity: No data available
10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Keep away from heat and other sources of ignition, including electrostatic discharge. Dust may form explosive mixture in air. 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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information in this section describes the hazards of various forms of the active ingredient. The toxicities of the two materials can be expected to be similar. The remaining information describes the potential hazards of the individual ingredients.

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

Chlortetracycline hydrochloride
Mouse Oral LD50 2314 mg/kg
Rat Oral LD50 > 3000mg/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
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)

Mineral oil
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

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

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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
11. TOXICOLOGICAL INFORMATION

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

**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

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data, below:

Toxicity:

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

**Chlortetracycline hydrochloride**
- **Daphnia magna** (Water Flea): OECD EC50 48 Hours > 541.1 mg/L
- **Pseudokirchneriella subcapitata** (Green Alga): OECD EC50 72 Hours 0.095 mg/L
- **Oncorhynchus mykiss** (Rainbow Trout): OECD LC50 96 Hours 59.5 mg/L

**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

Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

**Chlortetracycline hydrochloride**
- **Eisenia fetida** (Earthworm): OECD NOEC 56 Days 1000 mg/kg

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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.

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.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Chlortetracycline hydrochloride
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List 200-591-7

Mineral oil
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 232-384-2

Water
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
15. REGULATORY INFORMATION

Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

Calcium sulfate, dihydrate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List Not Listed

16. OTHER INFORMATION

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

H360 - May damage fertility or the unborn child

T - Toxic
R61 - May cause harm to the unborn child.

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


Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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