

SAFETY DATA SHEET



Revision date: 13-Dec-2013

Version: 1.0

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

Product Identifier

Material Name: Aureomycin® 50G

Trade Name: Aureomycin®
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product
Restrictions on Use: Not for human use

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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 to reproduction: Category 1

EU Symbol: T

EU Risk Phrases:
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger

Hazard Statements: H360D - May damage the unborn child
May form combustible dust concentrations in air

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Precautionary Statements: 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
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
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

Supplemental Hazards: Powdered material may form explosive dust-air mixtures



Other Hazards

Short Term: May cause hypersensitivity reactions in susceptible individuals. May cause stomach irritation, diarrhea, nausea, or vomiting. May cause eye, skin and respiratory tract irritation May cause adverse blood effects

Long Term: May cause damage to liver and kidneys

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|----------------------------|------------|-----------------------|-------------------|----------------------------|-------|
| Chlortetracycline | 57-62-5 | 200-341-7 | Repr. Cat.1;R61 | Repro. Tox. Cat. 1A (H360) | 46-50 |
| Calcium sulfate, dihydrate | 10101-41-4 | Not Listed | Not Listed | Not Listed | 45-49 |
| Mineral oil | 8012-95-1 | 232-384-2 | Not Listed | Not Listed | 0-5 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|------------|------------|-----------------------|-------------------|--------------------|-----|
| Water | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | 0-5 |

Additional Information: 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

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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:** Breathing dust may worsen asthma symptoms.

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

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 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

Avoid dust formation. 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:** Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spilled material by a method that controls dust generation. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and 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.

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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 contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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

| | |
|---------------------|-----------------------|
| Zoetis OEL TWA 8-hr | 0.5 mg/m ³ |
| Latvia OEL - TWA | 0.1 mg/m ³ |

Calcium sulfate, dihydrate

| | |
|-----------------------------------|-----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Germany (DFG) - MAK | 1.5 mg/m ³ |
| | 4 mg/m ³ |
| Vietnam O EL - TWAs | 6 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |

Mineral oil

| | |
|-----------------------------------|-----------------------|
| ACGIH Threshold Limit Value (TWA) | 5 mg/m ³ |
| Australia TWA | 5 mg/m ³ |
| Belgium OEL - TWA | 5 mg/m ³ |
| Bulgaria OEL - TWA | 5.0 mg/m ³ |
| Czech Republic OEL - TWA | 5 mg/m ³ |
| Denmark OEL - TWA | 1 mg/m ³ |
| Finland OEL - TWA | 5 mg/m ³ |
| Greece OEL - TWA | 5 mg/m ³ |
| Lithuania OEL - TWA | 1 mg/m ³ |
| Netherlands OEL - TWA | 5 mg/m ³ |
| Vietnam O EL - TWAs | 5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 5 mg/m ³ |
| Poland OEL - TWA | 5 mg/m ³ |
| Portugal OEL - TWA | 5 mg/m ³ |
| Romania OEL - TWA | 5 mg/m ³ |
| Slovakia OEL - TWA | 5 ppm |
| | 1 mg/m ³ |
| | 5 mg/m ³ |
| Spain OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 1 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 aerosols. Keep airborne contamination levels below the exposure limits listed above in this section. |
| 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: | Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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: | Granular solid | Color: | Brown |
| Odor: | Slight | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solvent Solubility: | No data available | | |
| Water Solubility: | Slightly Soluble: | | |
| pH: | 7-9 | | |
| 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 | |

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: | Dust may form explosive mixture in air. Fine particles (such as dusts, mists and vapors) may fuel fires/explosions. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge). |
| Incompatible Materials: | As a precautionary measure, keep away from strong oxidizers |

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10. STABILITY AND REACTIVITY

Hazardous Decomposition Products:

Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological properties of the formulation have not been fully investigated. The following information is available for the individual ingredients. The information in this section describes the hazards of various forms of the active ingredient.

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

Chlortetracycline

Rat Oral LD50 3000 mg/kg

Oxytetracycline

Mouse Oral LD50 > 5200 mg/kg

Rat Oral LD50 4800mg/kg

Mouse Subcutaneous LD50 > 3500mg/kg

Inhalation Acute Toxicity

Inhalation of dust may cause irritation of the respiratory tract and mucous membranes and allergic reactions in susceptible individuals.

Mineral oil

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

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

Chlortetracycline

6 Week(s) Mouse Oral 100 mg/kg/day NOAEL No effects at maximum dose

14 Week(s) Mouse Oral 200 mg/kg/day NOAEL No effects at maximum dose

14 Week(s) Rat Oral 200 mg/kg/day NOAEL No effects at maximum dose

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

Chlortetracycline

2 Generation Reproductive Toxicity Rat Oral 500 mg/kg/day NOAEL Negative

Oxytetracycline

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rat Intramuscular 41.5 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rabbit Intramuscular 41.5 mg/kg/day LOEL Embryotoxicity

Embryo / Fetal Development Dog Intramuscular 20.75 mg/kg/day LOEL Embryotoxicity, Teratogenic

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

Chlortetracycline

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

In Vitro HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative

In Vitro Unscheduled DNA Synthesis Rat Hepatocyte Negative

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11. TOXICOLOGICAL INFORMATION

In Vivo Chromosome Aberration Rat Negative

Oxytetracycline

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Positive with activation
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
Micronucleus Mouse Negative

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

Chlortetracycline

2 Year(s) Rat Oral 700 mg/kg/day NOAEL Not carcinogenic

Oxytetracycline

103 Week(s) Rat Oral, in feed 2094 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: Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Oxytetracycline

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours < 200 mg/L

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.

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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

| | |
|---|--------------------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 Schedule 5 |
| EU EINECS/ELINCS List | 200-341-7 |

Calcium sulfate, dihydrate

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |

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

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16. OTHER INFORMATION

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

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

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.

Reasons for Revision: New data sheet.

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