

# SAFETY DATA SHEET



Revision date: 19-Dec-2013

Version: 2.0

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## 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

**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

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

700139 / 700138

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**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.  
Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

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

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

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**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

**Measures 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.

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**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/m<sup>3</sup>

#### Mineral oil

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

#### Calcium sulfate, dihydrate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>

#### 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:

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.

### 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
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### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	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.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	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

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### 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 foetida* (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

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### 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



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### 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.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**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**