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

Product Identifier

Material Name: Aureo® S-P 250G

Trade Name: AUREO®

Chemical Family: Mixture

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

Intended Use: Veterinary product

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 granular solid

Classification of the Substance or Mixture

GHS - Classification
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Reproductive Toxicity: Category 1A

EU Classification:
EU Indication of danger: Toxic to reproduction: Category 1
Xn - Harmful
EU Symbol: T Xn
EU Risk Phrases:
R61 - May cause harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

Label Elements

Signal Word: Danger
Hazard Statements:
H360D - May damage the unborn child
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P284 - Wear respiratory protection
P362 - Take off contaminated clothing and wash before reuse
P272 - Contaminated work clothing should not be allowed out of the workplace
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P304 + P313 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P405 - Store locked up
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards Short Term:

May cause stomach irritation, diarrhea, nausea, or vomiting. May cause liver and kidney effects
May cause adverse blood effects
May cause eye, skin and respiratory tract irritation

Australian Hazard Classification (NOHSC):


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

<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>Calcium carbonate</td>
<td>1317-65-3</td>
<td>215-279-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>60-100</td>
</tr>
<tr>
<td>Silica gel</td>
<td>63231-67-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>0-5</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>0-5</td>
</tr>
<tr>
<td>Chlortetracycline</td>
<td>57-62-5</td>
<td>200-341-7</td>
<td>Repr. Cat.1;R61</td>
<td>Repro. Tox. Cat. 1A (H360D)</td>
<td>4.4</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>57-68-1</td>
<td>200-346-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>4.4</td>
</tr>
<tr>
<td>Procaine Penicillin G monohydrate</td>
<td>6130-64-9</td>
<td>Not Listed</td>
<td>Xn;R42/43</td>
<td>Resp. Sens. 1 (H334) Skin Sens. 1 (H317)</td>
<td>2.2</td>
</tr>
</tbody>
</table>
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
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.

Calcium carbonate
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 1.0 fiber/cm³, 10.0 mg/m³
- Czech Republic OEL - TWA: 10.0 mg/m³
- Estonia OEL - TWA: 10 mg/m³
- Greece OEL - TWA: 5 mg/m³
- Hungary OEL - TWA: 10 mg/m³
- Ireland OEL - TWA: 10 mg/m³
- OSHA - Final PELS - TWAs: 4 mg/m³
- Slovakia OEL - TWA: 10 mg/m³
- Switzerland OEL - TWAs: 3 mg/m³

Silica gel
- Australia TWA: 10 mg/m³
- Slovenia OEL - TWA: 4 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithuania</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Netherlands</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1 ppm</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>

#### Chlortetracycline
- **Zoetis OEL TWA 8-hr**: 0.5 mg/m³
- **Latvia OEL - TWA**: 0.1 mg/m³

#### Sulfamethazine
- **Latvia OEL - TWA**: 1 mg/m³
- **Lithuania OEL - TWA**: 1 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Sulfamethazine**

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoetis OEL</td>
<td>OEB 2</td>
</tr>
</tbody>
</table>

**Exposure Controls**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Granular solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Slight</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>Brown</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Slightly Soluble:</td>
</tr>
<tr>
<td>pH</td>
<td>5.5 - 7.5</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

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.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
  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.

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

Chlortetracycline
  Rat  Oral  LD50  3000 mg/kg

Sulfamethazine
  Mouse  Oral  LD50  50 g/kg
  Mouse  Sub-tenon injection (eye)  LD50  1.06 g/kg

Procaine Penicillin G monohydrate
  Mouse  Oral  LD50  > 2000 mg/kg
  Rat  Para-periosteal  LD50  97 mg/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.
11. TOXICOLOGICAL INFORMATION

Inhalation Acute Toxicity

Allergic reactions might occur based on effects of the individual components. Inhalation of dust may cause irritation of the respiratory tract and mucous membranes and allergic reactions in susceptible individuals.

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)

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

Sulfamethazine

Reproductive & Fertility  Mouse  Oral 805 mg/kg/day  NOEL  Fertility
Embryo / Fetal Development  Rat  Oral 545 mg/kg/day  NOEL  Teratogenic
Reproductive & Fertility  Rabbit  Oral 600 mg/kg/day  NOEL  Not Teratogenic, Maternal Toxicity, Fetotoxicity

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
In Vivo Chromosome Aberration  Rat  Negative

Sulfamethazine

Bacterial Mutagenicity (Ames)  Salmonella  Negative
Chromosome Aberration Chinese Hamster Ovary (CHO) cells  Negative
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells  Positive

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

Chlortetracycline

2 Year(s)  Rat  Oral 700 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.

Sulfamethazine

IARC:  Group 3 (Not Classifiable)
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

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
Class D, Division 2, Subdivision B
15. REGULATORY INFORMATION

Calcium carbonate
- 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: 215-279-6

Silica gel
- 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: 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

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
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS/ELINCS List: 200-341-7

Sulfamethazine
- 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
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS/ELINCS List: 200-346-4

Procaine Penicillin G monohydrate
- 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
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Toxic to reproduction: Category 1
Xn - Harmful
R61 - May cause harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

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 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification.

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