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

Product Identifier

Material Name: Trimethoprim and Sulfadiazine Powder (Animal Health)
Trade Name: TUCOPRIM(R), UNIPRIM(R)
Chemical Family: Mixture

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

2. HAZARDS IDENTIFICATION

Appearance: White to off-white powder

Classification of the Substance or Mixture

GHS - Classification
- Acute Oral Toxicity: Category 4
- Reproductive Toxicity: Category 2

US OSHA Specific - Classification
- Physical Hazard: Combustible Dust

EU Classification:
- EU Indication of danger: Harmful
- Toxic to Reproduction: Category 3

EU Symbol: Xn
EU Risk Phrases:
- R22 - Harmful if swallowed.
- R63 - Possible risk of harm to the unborn child.

Label Elements
- Signal Word: Warning
- Hazard Statements:
  - H302 - Harmful if swallowed
  - H361 - Suspected of damaging fertility or the unborn child
  - May form combustible dust concentrations in air
Precautionary Statements:  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
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  
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
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:
Dust may cause irritation

Known Clinical Effects:
Adverse effects associated with therapeutic use include nausea, diarrhea, blood cell changes, muscle pain, skin rash, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis), kidney toxicity (nephrotoxicity). Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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>EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>200-685-8</td>
<td>Xn;R22</td>
<td>Acute Tox. 4,H302</td>
<td>33</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>212-006-2</td>
<td>T;R25 Repr.Cat.3;R63</td>
<td>Acute Tox. Cat. 3 (H301) Repro. Tox. Cat. 2 (H361)</td>
<td>7</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: 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: Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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. 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. Wipe up with a damp cloth and place in container for disposal. Clean contaminated surface thoroughly.
Additional Consideration for Large Spills: 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 contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment.

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

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>France OEL</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Poland OEL</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Sulfadiazine

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoetis OEL</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Lithuania</td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>

Trimethoprim

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoetis OEL</td>
<td>100 µg/m³</td>
</tr>
</tbody>
</table>

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: 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: 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Powder</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
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</tr>
<tr>
<td>Relative Density</td>
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</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C)</td>
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</tr>
<tr>
<td>Flammability (Solids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
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</tr>
</tbody>
</table>

## 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Oxidizing Properties:</strong></td>
<td></td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions. Keep away from heat, spark, flames and all other sources of ignition.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

## 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects:

General Information: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

Calcium carbonate
11. TOXICOLOGICAL INFORMATION

Trimethoprim
- **Rat** Oral LD50 200 mg/kg
- **Rat** Sub-tenon injection (eye) LD50 500 mg/kg
- **Mouse** Oral LD50 2764 mg/kg
- **Mouse** Intraperitoneal LD50 200 mg/kg
- **Mouse** Intravenous LD50 1870 mg/kg

**Sulfadiazine**
- **Mouse** Oral LD 50 1500 mg/kg

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

**Trimethoprim**
- Reproductive & Fertility - Males **Rat** Oral 70 mg/kg/day NOAEL Fertility
- Reproductive & Fertility - Females **Rat** Oral 14 mg/kg/day NOAEL Fertility
- Embryo / Fetal Development **Rabbit** Oral 30 mg/kg LOAEL Embryotoxicity
- Embryo / Fetal Development **Rat** Oral 200 mg/kg LOAEL Maternal Toxicity, Teratogenic
- Embryo / Fetal Development **Mouse** Oral 70 mg/kg NOAEL Not Teratogenic

**Sulfadiazine**
- Embryo / Fetal Development **Rat** Oral 500 mg/kg/day NOEL Not teratogenic
- Embryo / Fetal Development **Mouse** Oral 500 mg/kg/day NOEL Not Teratogenic

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

**Trimethoprim**
- Bacterial Mutagenicity (Ames) *Salmonella, E. coli* Negative
- In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
- In Vitro Chromosome Aberration Human Lymphocytes Negative

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

Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)
Revision date: 13-Mar-2014

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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

Trimethoprim
*Daphnia magna* (Water Flea) OECD LC50 48 Hours 141 mg/L

Sulfadiazine
*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours 3.43 mg/L
*Daphnia magna* (Water Flea) OECD EC50 48 Hours 212-221 mg/L
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 103.0 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Sulfadiazine
Predicted 7 Log D -0.68

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
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

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 207-439-9

Sulfadiazine
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
EU EINECS/ELINCS List 207-439-9

Trimethoprim
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List 212-006-2

16. OTHER INFORMATION

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

H302 - Harmful if swallowed
H301 - Toxic if swallowed
H361 - Suspected of damaging fertility or the unborn child

Xn - Harmful
T - Toxic
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.
R25 - Toxic if swallowed.
R63 - Possible risk of 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.
SAFETY DATA SHEET

Material Name:  Trimethoprim and Sulfadiazine Powder (Animal Health)
Revision date: 13-Mar-2014

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. 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 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