

SAFETY DATA SHEETS

This SDS packet was issued with item:

078475786

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078414899

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078414907



MATERIAL SAFETY DATA SHEET

Revision date: 07-Dec-2006

Version: 2.1

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Trimethoprim and Sulfadiazine Powder (Animal Health)

Trade Name: TUCOPRIM(R), UNIPRIM(R)
Chemical Family: Mixture
Intended Use: Veterinary product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Trimethoprim	738-70-5	212-006-2	7
Calcium carbonate	471-34-1	207-439-9	*
Sulfadiazine	68-35-9	200-685-8	33

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white powder
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Possible risk of harm to the unborn child

Additional Hazard Information:

Short Term: Harmful if swallowed (based on animal data).
Known Clinical Effects: Adverse effects associated with the 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.

EU Indication of danger: Harmful
Toxic to Reproduction; Category 3

EU Hazard Symbols:



MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)

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EU Risk Phrases:

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits fumes of carbon dioxide sulfur oxides , nitrogen oxides .

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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.

7. HANDLING AND STORAGE

General Handling: Avoid breathing dust. Avoid contact with eyes, skin and clothing. Minimize dust generation and accumulation. Wash thoroughly after handling. Use with adequate ventilation.

Storage Conditions: Store as directed by product packaging.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Trimethoprim

Pfizer OEL TWA-8 Hr: 0.1mg/m³

Calcium carbonate

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA particulate matter containing no asbestos and <1% crystalline silica

ACGIH OELs - Notice of Intended Changes Listed

Australia TWA = 10 mg/m³ TWA

Sulfadiazine

Pfizer OEL TWA-8 Hr: 2 mg/m³

Analytical Method: Analytical method available for sulfadiazine; trimethoprim. Contact Pfizer Inc for further information.

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

Personal Protective Equipment:

Hands: Wear impervious gloves.

Eyes: Safety glasses or goggles

Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.

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:	Powder	Color:	White to off-white
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Calcium carbonate

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Rat Oral LD50 6450 mg/kg

Trimethoprim

Rat Oral LD50 200 mg/kg
Rat Intraperitoneal LD50 500 mg/kg
Mouse Oral LD50 2764 mg/kg
Mouse Intravenous LD50 200 mg/kg
Mouse Intraperitoneal 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
Reproductive & Fertility	Rabbit	Oral	250 mg/kg/day	NOEL	Not Teratogenic

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

Trimethoprim

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative

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 have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)

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15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
Toxic to Reproduction; Category 3

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

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
Possible risk of harm to the unborn child

Canada - WHMIS: Classifications

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



Trimethoprim

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	212-006-2

Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	207-439-9

Sulfadiazine

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 List	200-685-8

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)

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16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.
Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer 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.

End of Safety Data Sheet

SAFETY DATA SHEET



Revision date: 13-Mar-2014

Version: 3.0

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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

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: 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

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Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)
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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:

Known Clinical Effects:

Dust may cause irritation

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):

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	%
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Sulfadiazine	68-35-9	200-685-8	Xn;R22	Acute Tox. 4,H302	33
Trimethoprim	738-70-5	212-006-2	T;R25 Repr.Cat.3;R63	Acute Tox. Cat. 3 (H301) Repro. Tox. Cat. 2 (H361)	7

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

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Material Name: Trimethoprim and Sulfadiazine Powder
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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:** 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.

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Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)
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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

Australia TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
France OEL - TWA	10 mg/m ³
Latvia OEL - TWA	6 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³

Sulfadiazine

Zoetis OEL TWA 8-hr	2 mg/m ³
Lithuania OEL - TWA	1 mg/m ³

Trimethoprim

Zoetis OEL TWA 8-hr	100 µg/m ³
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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.

SAFETY DATA SHEET

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

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	White to off-white
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

Sulfadiazine

Predicted 7 Log D -0.68

Decomposition Temperature (°C):	No data available.
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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:	Fine particles (such as dust and mists) may fuel fires/explosions. Keep away from heat, spark, flames and all other sources of ignition.
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: 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

SAFETY DATA SHEET

Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)
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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 6450 mg/kg

Trimethoprim

Rat Oral LD50 200 mg/kg

Rat Sub-tenon injection (eye) LD50 500mg/kg

Mouse Oral LD50 2764mg/kg

Mouse Intravenous LD50 200mg/kg

Mouse Intraperitoneal LD50 1870mg/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 NOEL Fertility

Reproductive & Fertility - Females Rat Oral 14 mg/kg/day NOEL 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

Reproductive & Fertility Rabbit Oral 250 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.

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Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)
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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

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Material Name: Trimethoprim and Sulfadiazine Powder
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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	Schedule 5 200-685-8

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.

TRIMETHOPRIM AND SULFADIAZINE POWDER

SAFETY DATA SHEET

**Material Name: Trimethoprim and Sulfadiazine Powder
(Animal Health)**

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Revision date: 13-Mar-2014

Version: 3.0

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

SAFETY DATA SHEET



Revision date: 13-Mar-2014

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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

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: 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

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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:

Known Clinical Effects:

Dust may cause irritation

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.

Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Sulfadiazine	68-35-9	200-685-8	Xn;R22	Acute Tox. 4,H302	33
Trimethoprim	738-70-5	212-006-2	T;R25 Repr.Cat.3;R63	Acute Tox. Cat. 3 (H301) Repro. Tox. Cat. 2 (H361)	7

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

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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:** 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.

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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

Australia TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
France OEL - TWA	10 mg/m ³
Latvia OEL - TWA	6 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³

Sulfadiazine

Zoetis OEL TWA 8-hr	2 mg/m ³
Lithuania OEL - TWA	1 mg/m ³

Trimethoprim

Zoetis OEL TWA 8-hr	100 µg/m ³
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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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	White to off-white
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

Sulfadiazine

Predicted 7 Log D -0.68

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: Fine particles (such as dust and mists) may fuel fires/explosions. Keep away from heat, spark, flames and all other sources of ignition.
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: 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

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 6450 mg/kg

Trimethoprim

Rat Oral LD50 200 mg/kg

Rat Sub-tenon injection (eye) LD50 500mg/kg

Mouse Oral LD50 2764mg/kg

Mouse Intravenous LD50 200mg/kg

Mouse Intraperitoneal LD50 1870mg/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 NOEL Fertility

Reproductive & Fertility - Females Rat Oral 14 mg/kg/day NOEL 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

Reproductive & Fertility Rabbit Oral 250 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.

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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

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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	Schedule 5 200-685-8

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.

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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