



MATERIAL SAFETY DATA SHEET

Revision date: 17-Jun-2010

Version: 1.2

Page 1 of 8

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

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Material Name: Trimethoprim/Sulfametopyrazine Capsules

Trade Name: KELFIPRIM®; TRIDIS®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Gray and yellow capsules
Signal Word: DANGER

Statement of Hazard: Toxic if swallowed.
Suspected of damaging the unborn child.

Additional Hazard Information:

Short Term: May be harmful if swallowed. (based on animal data) .

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

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.

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

EU Hazard Symbols:

Xn



EU Risk Phrases:

R25 - Toxic if swallowed.
R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 2 of 8
Version: 1.2

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Maize starch	9005-25-8	232-679-6	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Trimethoprim	738-70-5	212-006-2	T;R25 Repr.Cat.3;R63	50
Sulfadiazine	68-35-9	200-685-8	Not Listed	40
Magnesium Stearate	557-04-0	209-150-3	OEL	*

Additional Information: * Proprietary

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

4. 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.

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.

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: Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 3 of 8
Version: 1.2

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Maize starch

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m ³ TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	2.5 mg/m ³ containing no asbestos fibers
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 4 of 8
Version: 1.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Trimethoprim

Pfizer OEL TWA-8 Hr: 100µg/m³

Sulfadiazine

Pfizer OEL TWA-8 Hr: 2000µg/m³
Lithuania OEL - TWA Listed

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Ireland OEL - TWAs Listed
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs Listed

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. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

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:

Capsule

Color:

Gray and yellow

Molecular Formula:

Mixture

Molecular Weight:

Mixture

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 5 of 8
Version: 1.2

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
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)

Trimethoprim

Rat Oral LD50 200 mg/kg
Rat Sub-tenon injection (eye) 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

Talc (non-asbestiform)

Rat Oral LD50 > 1600 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.

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

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

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

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 6 of 8
Version: 1.2

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

**Talc (non-asbestiform)
IARC:** Group 3

12. ECOLOGICAL INFORMATION

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

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 88.0 mg/L

Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 103.0 mg/L

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

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic
Toxic to Reproduction: Category 3

EU Risk Phrases:
R25 - Toxic if swallowed.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:

MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 7 of 8
Version: 1.2

15. REGULATORY INFORMATION

S22 - Do not breathe dust.
S28 - After contact with skin, wash immediately with plenty of water.
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER

Toxic if swallowed.

Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision B

Class D, Division 2, Subdivision A



Maize starch

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	238-877-9

Trimethoprim

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

Sulfadiazine

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5
EU EINECS/ELINCS List	200-685-8

Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
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MATERIAL SAFETY DATA SHEET

Material Name: Trimethoprim/Sulfametopyrazine Capsules
Revision date: 17-Jun-2010

Page 8 of 8
Version: 1.2

15. REGULATORY INFORMATION

Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic if swallowed.

R63 - Possible risk of harm to the unborn child.

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: 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 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet