



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

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

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

**Pfizer Ltd**  
Ramsgate Road  
Sandwich, 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/Sulfametopyrazine Capsules

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

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Maize starch	9005-25-8	232-679-6	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Trimethoprim	738-70-5	212-006-2	50
Magnesium Stearate	557-04-0	209-150-3	*
Sulfadiazine	68-35-9	200-685-8	40

**Additional Information:** \* Proprietary

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Gray and yellow capsules  
**Signal Word:** WARNING

**Statement of Hazard:** Harmful if swallowed.  
Possible risk of harm to 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 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:** Toxic  
Toxic to Reproduction; Category 3

**EU Hazard Symbols:**

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### EU Risk Phrases:

R25 - Toxic 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:** 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.

**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

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**General Handling:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Maize starch

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA  
Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

### Trimethoprim

Pfizer OEL TWA-8 Hr: 0.1mg/m<sup>3</sup>

### Magnesium Stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Sulfadiazine

Pfizer OEL TWA-8 Hr: 2 mg/m<sup>3</sup>  
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**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:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. 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  
**Molecular Formula:** Mixture  
**Color:** Gray and yellow  
**Molecular Weight:** Mixture

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### 10. STABILITY AND REACTIVITY

**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 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

##### 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

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

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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.

## 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.

## 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:**  
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:**  
WARNING  
Harmful if swallowed.  
Possible risk of harm to the unborn child

**Canada - WHMIS: Classifications**

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## WHMIS hazard class:

Class D, Division 1, Subdivision B  
Class D, Division 2, Subdivision A



## Maize starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

## Talc (non-asbestiform)

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

## Trimethoprim

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

## Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

## 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

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**