



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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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 Syrup

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Titanium dioxide	13463-67-7	236-675-5	*
Sucrose	57-50-1	200-334-9	*
Citric acid	77-92-9	201-069-1	*
Trimethoprim	738-70-5	212-006-2	1
Monoammonium glycyrrhizinate	53956-04-0	258-887-7	*
Sulfadiazine	68-35-9	200-685-8	<1

Ingredient	CAS Number	EU EINECS List	%
Agar	9002-18-0	232-658-1	*
Licorice Essence	Not Assigned	Not listed	*
Methylparaben	99-76-3	202-785-7	*
Propylparaben	94-13-3	202-307-7	*
Water, purified	7732-18-5	231-791-2	*
Ethylparaben	120-47-8	204-399-4	*
Polysorbate 20	9005-64-5	Not listed	*
Sodium saccharin USP	128-44-9	204-886-1	*
Cocoa Extract	NOT ASSIGNED	Not listed	*

Additional Information: * Proprietary

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

3. HAZARDS IDENTIFICATION

Appearance: Brown liquid
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
Possible risk of harm to the unborn child

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Additional Hazard Information:

Short Term:

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) and 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:

Not classified

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 spill with absorbent material. 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.

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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 contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

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

Sucrose

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

Trimethoprim

Pfizer OEL TWA-8 Hr:	0.1mg/m ³
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Sulfadiazine

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

Analytical Method: Analytical method available for trimethoprim; sulfadiazine. 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:	Liquid	Color:	Brown
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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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)

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

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Sodium saccharin USP

Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/kg

Methylparaben

Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal LD 50 200 mg/kg

Sucrose

Rat Oral LD50 29.7 g/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.

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

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4 Week(s) Rat Oral 347.2 mg/kg LOEL Male reproductive system

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	LOEL	Embryotoxicity
Embryo / Fetal Development	Rat	Oral	200 mg/kg	LOEL	Maternal Toxicity, Teratogenic
Embryo / Fetal Development	Mouse	Oral	70 mg/kg	NOEL	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: See below

Titanium dioxide

IARC: Group 2B
OSHA: Present

Sodium saccharin USP

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.

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15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

WARNING

May be harmful if swallowed.

Possible risk of harm to the unborn child

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Agar

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-658-1

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Ethylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-399-4

Polysorbate 20

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
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Australia (AICS):	Present
EU EINECS List	236-675-5
Sucrose	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9
Citric acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1
Trimethoprim	
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	212-006-2
Sodium saccharin USP	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1
Monoammonium glycyrrhizinate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	258-887-7
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 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet