



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

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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: Cefpodoxime Proxetil Tablets 100 mg and 200 mg

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Cefpodoxime Proxetil	87239-81-4	Not listed	100 or 200 mg***
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Magnesium Stearate	557-04-0	209-150-3	*
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Carboxy methylcellulose calcium	9050-04-8	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Lactose Monohydrate	64044-51-5	Not listed	*
Propylene glycol	57-55-6	200-338-0	*
FD & C Red No. 40	25956-17-6	247-368-0	*
D & C yellow No. 10	8004-92-0	Not listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
Carnauba wax	8015-86-9	232-399-4	*
Hypromellose	9004-65-3	Not listed	*

Additional Information:

* Proprietary

*** per tablet/capsule/lozenge/suppository

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

3. HAZARDS IDENTIFICATION

Appearance: Orange tablets or Red tablets
Signal Word: WARNING

Statement of Hazard: May cause sensitization by inhalation and skin contact
Additional Hazard Information:

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Short Term: Not expected to cause eye irritation. Not expected to cause skin irritation. May cause allergic reaction in penicillin-sensitive individuals. Not acutely toxic (based on animal data). Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may occur.

Known Clinical Effects: Harmful

EU Indication of danger: Harmful

EU Hazard Symbols:



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

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: 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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.

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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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Cefpodoxime Proxetil
Pfizer OEL TWA-8 Hr: 0.1mg/m³, Sensitizer

Propylene glycol
Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

Magnesium Stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Titanium dioxide
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.

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: Tablets
Color: Orange or Red
Molecular Formula: Mixture
Molecular Weight: Mixture

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10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Polymerization: Will not occur

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)

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg
Mouse Oral LD50 > 6,000 mg/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

D & C yellow No. 10

Rat Oral LD50 2000 mg/kg

Titanium dioxide

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

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg
Rat Intraperitoneal LD 50 210 mg/kg

Cefpodoxime Proxetil

Mouse Oral LD 50 > 8000 mg/kg
Mouse Intraperitoneal LD 50 2535 mg/kg
Mouse Subcutaneous LD 50 > 10,000 mg/kg
Rat Intravenous LD 50 > 4000 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 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.

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

Propylene glycol

Skin Irritation Rabbit Mild

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Eye Irritation Rabbit Mild

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Eye Irritation Rabbit Minimal

Skin Irritation Rabbit No effect

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

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

Magnesium Stearate

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

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

Cefpodoxime Proxetil

Reproductive & Fertility Rat Oral > 500 mg/kg/day NOAEL Fertility

Reproductive & Fertility Rabbit Oral > 500 mg/kg/day NOAEL Fertility

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

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

Cefpodoxime Proxetil

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Chromosome Aberration Negative

Unscheduled DNA Synthesis Negative

In Vivo Micronucleus Negative

Carcinogen Status: See below

FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

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.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases: R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases: S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause sensitization by inhalation and skin contact

Canada - WHMIS: Classifications

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



Carboxy methylcellulose calcium	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Hydroxypropyl cellulose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Sodium Lauryl Sulfate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1
Lactose Monohydrate	
Australia (AICS):	Present
Propylene glycol	

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0
FD & C Red No. 40	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	247-368-0
D & C yellow No. 10	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
FD&C Yellow No. 6; (Sunset yellow)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	220-491-7
Carnauba wax	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-399-4
Magnesium Stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
Hypromellose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
Titanium dioxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. 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 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Prepared by:

Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet