



MATERIAL SAFETY DATA SHEET

Revision date: 01-Nov-2004

Version: 1.0

Page 1 of 6

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

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Pfizer Pharmaceuticals Group
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Hours of Operation - 24 Hours

Emergency telephone number: 1-212-573-2222
Hours of Operation - 24 Hours
Telephone: 01304 616161
(Pfizer Ltd Main Exchange)

Material Name: Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg

Synonyms: Cefpodoxime Proxetil Tablets
Intended Use: Veterinary antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS List:	Classification	%
Cefpodoxime Proxetil	87239-81-4	Not Listed	Not Listed	30.3
Carboxy methylcellulose calcium	9050-04-8	Not Listed	Not Listed	17.9
Water	7732-18-5	231-791-2; H2O	Not Listed	42.5
SD Alcohol 3A	Not assigned	Not Listed	Not Listed	6
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	1.5
Sodium Lauryl Sulfate	151-21-3	Not Listed	Not Listed	<1.0
Magnesium Stearate	557-04-0	209-150-3; C18H36O2.1/2Mg 231-104-6; Mg	Not Listed	<1.0
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	<1.0

3. HAZARDS IDENTIFICATION

Appearance: Orange tablets
Signal Word: WARNING

Statement of Known Hazard (GHS Classification): May cause allergic reaction

Potential Health Effects: 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 cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

Potential Environmental Effects: Not determined

Potential Physical / Chemical Hazards: Not determined

EU Indication of danger: Xn - Harmful

MATERIAL SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**
Revision date: 01-Nov-2004

Page 2 of 6

Version: 1.0



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

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.

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.

Notes to Physician: None

Medical Conditions Aggravated by Exposure: None known

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

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: 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

MATERIAL SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**
Revision date: 01-Nov-2004

Page 3 of 6

Version: 1.0

General Handling: Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pfizer OEL: 0.1 mg/m³ (Cefpodoxime)

Laboratory Scale:

Engineering Controls: Engineering controls should be used as a primary means of containment. Perform operations in a ventilated enclosure.

Personal Protective Equipment: Wear safety glasses, protective gloves and a laboratory coat when handling this compound.

Pilot Plant Scale:

Engineering Controls: Engineering controls should be used as a primary means of containment. Handle in enclosed systems or under suitable local exhaust systems.

Personal Protective Equipment: Wear safety glasses, protective gloves, coveralls, and protective boots when handling this compound. Evaluate additional respiratory protection, as needed based on available engineering controls.

Manufacturing Scale:

Engineering Controls: Engineering controls should be used as a primary means of containment. Handle in enclosed systems or under suitable local exhaust systems.

Personal Protective Equipment: Wear safety glasses, protective gloves, coveralls, and protective boots when handling this compound. Evaluate additional respiratory protection, as needed based on available engineering controls.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	Color:	Orange
Molecular Formula:	No data available.	Molecular Weight:	No data available.

Additional Information: The characteristics of this compound have not been fully determined.

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions

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

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

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The following information is available for the individual ingredients.

MATERIAL SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**
Revision date: **01-Nov-2004**

Page 4 of 6

Version: 1.0

Acute Toxicity

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

Magnesium Stearate

Rat Oral LD 50 1092 gm/kg/13 weeks

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Irritation / Sensitization

Cefpodoxime Proxetil

Eye Irritation Rabbit Positive Minimal
Skin Irritation Rabbit Negative No effect

Reproduction & Developmental Toxicity

Cefpodoxime Proxetil

Reproductive & Fertility Rat Oral >500 mg/kg/day NOEL Fertility
Reproductive & Fertility Rabbit Oral >500 mg/kg/day NOEL Fertility
Embryo/Fetal Development Rat Oral 100 mg/kg/day NOEL Not Teratogenic, Fetotoxicity
Embryo/Fetal Development Rabbit Oral 30 mg/kg/day NOEL Not Teratogenic, Fetotoxicity

Genetic Toxicity

Cefpodoxime Proxetil

Bacterial Mutagenicity (Ames) Salmonella Negative
Chromosome Aberration Negative
Unscheduled DNA Synthesis Negative
In Vivo Micronucleus Negative

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

The following refers to all categories of classifications unless specified below.

This material is not regulated for transportation / carriage.

MATERIAL SAFETY DATA SHEET

Material Name: Simplicef (Cefpodoxime Proxetil) Tablets - 100
and 200 mg
Revision date: 01-Nov-2004

Page 5 of 6

Version: 1.0

15. REGULATORY INFORMATION

EU Labeling:

EU Indication of danger: Xn - 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.

EU EINECS List:

Not Listed

EU ELINCS List:

Not Listed

Cefpodoxime Proxetil

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

Carboxy methylcellulose calcium

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

Water

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

SD Alcohol 3A

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

Hydroxypropyl cellulose

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

Sodium Lauryl Sulfate

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

Magnesium Stearate

CERCLA/SARA section 302 EHS TPQ	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

Lactose Monohydrate

CERCLA/SARA section 302 EHS TPQ	Not Listed
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MATERIAL SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**
Revision date: 01-Nov-2004

Page 6 of 6

Version: 1.0

CERCLA/SARA 313 Emission reporting
California Proposition 65

Not Listed
Not Listed

CERCLA Reportable Quantity: Not determined
OSHA Label:
WARNING
May cause allergic reaction

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials
D2b toxic materials

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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