



MATERIAL SAFETY DATA SHEET

Revision date: 13-Jun-2008

Version: 1.2

Page 1 of 10

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

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Material Name: Cefdinir Capsules

Trade Name:	OMNICEF®
Chemical Family:	Cephalosporin antibiotic
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Red and blue capsules
Signal Word: WARNING

Statement of Hazard: May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

Additional Hazard Information:
Short Term: If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. 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. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

EU Indication of danger: Harmful

EU Hazard Symbols:
Xn



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 2 of 10
Version: 1.2

2. HAZARDS IDENTIFICATION

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.
Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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	Classification	%
Cefdinir	91832-40-5	Not listed	Xn;R42/43	300 mg***
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Silicon dioxide, NF	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Gelatin	9000-70-8	232-554-6	Not Listed	*
D&C red #28	18472-87-21	Not listed	Not Listed	*
PEG-40 Stearate	9004-99-3	Not listed	Not Listed	*
FD & C Red No. 40	25956-17-6	247-368-0	Not Listed	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	Not Listed	*
FD & C Blue No. 1	3844-45-9	223-339-8	Not Listed	*
Carboxy methylcellulose calcium	9050-04-8	Not listed	Not Listed	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository

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

For the full text of the R phrases mentioned in this Section, see Section 16

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.

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 3 of 10
Version: 1.2

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.

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).

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

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 4 of 10
Version: 1.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	= 1.5 mg/m ³ MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	= 10 mg/m ³ TWA = 4 mg/m ³ TWA
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	= 5 mg/m ³ LLV

Silicon dioxide, NF

Australia TWA	= 2 mg/m ³ TWA
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	= 4 mg/m ³ TWA
Germany (DFG) - MAK	= 4 mg/m ³ MAK
Ireland OEL - TWAs	= 2.4 mg/m ³ TWA = 6 mg/m ³ TWA
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO ₂) mg/m ³ TWA = 20 mppcf TWA
Slovenia OEL - TWA	Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA	
Belgium OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m ³ TWA	except lead stearate
Lithuania OEL - TWA	Listed	
Portugal OEL - TWA	Listed	
Spain OEL - TWA	Listed	
Sweden OEL - TWAs	= 5 mg/m ³ LLV	

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 5 of 10
Version: 1.2

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:	Red and blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: Not determined

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)

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 6 of 10
Version: 1.2

Sodium Lauryl Sulfate

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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Silicon dioxide, NF

Rat Oral LD50 10 g/kg

Titanium dioxide

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

PEG-40 Stearate

Rat Oral LD50 > 20,000 mg/kg

Cefdinir

Dog Oral LD50 > 3200 mg/kg
Mouse Oral LD50 > 5600 mg/kg
Rat Oral LD50 > 5600 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)

Cefdinir

Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Minimal
Antigenicity- Active anaphylaxis Guinea Pig Negative

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

Cefdinir

26 Week(s) Rat Oral 320 mg/kg/day LOAEL Gastrointestinal System
26 Week(s) Dog Oral 800 mg/kg/day NOAEL None identified

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

Cefdinir

Reproductive & Fertility Rat Oral 1000 mg/kg/day LOEL Maternal toxicity
Embryo / Fetal Development Rat Oral 100 mg/kg/day LOEL Maternal Toxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOEL Maternal Toxicity, Not Teratogenic
Peri-/Postnatal Development Rat Oral 32 mg/kg/day LOEL Maternal Toxicity, Developmental toxicity

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 7 of 10
Version: 1.2

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

Cefdinir

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Chromosome Aberration Negative

In Vivo Micronucleus Mouse Negative

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

FD & C Blue No. 1

IARC: Group 3 (Not Classifiable)

Silicon dioxide, NF

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 8 of 10
Version: 1.2

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 9 of 10
Version: 1.2

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.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

Canada - WHMIS: Classifications

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



Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6

PEG-40 Stearate

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

FD & C Red No. 40

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	247-368-0

Sodium Lauryl Sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-788-1

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

MATERIAL SAFETY DATA SHEET

Material Name: Cefdinir Capsules
Revision date: 13-Jun-2008

Page 10 of 10
Version: 1.2

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 EEC No. 418-260-2

FD & C Blue No. 1

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	223-339-8

Magnesium stearate

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

Carboxy methylcellulose calcium

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. 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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. 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