Cefaclor for Oral Suspension

Effective Date: 25-Mar-2006

Eli Lilly and Company
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Cefaclor for Oral Suspension

Chemical Name: 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[(2R)-aminophenylacetyl] amino]-3-chloro-8-oxo-, monohydrate, (6R,7R)-
Chemical Name 2: 3-Chloro-7-D-(2-phenylglycinamido)-3-cephem-4-carboxylic acid monohydrate
Synonym(s): Ceclor BD; Ceclor BD Forte; Cefaclor Granulation for Oral Suspension; Cefaclor RPG; Cefaclor Oral Granulation; Cefaclor; Cefaclor Granules; 099638 Formulation; Alfatil Sachets; Kloclor; Kloclor BD; Kloclor Forte
Trademarks(s): Ceclor; Alfatil; Distaclor; Kefalor; Keflor; Kefolor; Panacef
Lilly Item Code(s): CA1455; CK0987; MS5057; MS5058; MS5061; MS5077; MS5078; MS5086; MS5116; MS5117; MS5129; MS5130; MS5132; MS5133; MS5148; MS8990; MS8998; ND0727; ND0728; ND0830; ND0831; ND0840; ND0876; ND0890; ND0891; ND0892; ND0893; ND0950; ND0951; ND0980; QA420J; UC0006; UC0007; UC0008; UC5006; UC5007; UC5008; UC5009; UC5365; UC5366; UC5367; UC5903; UC5904; UC5913; UC5914; UC5915; UC5916; UC5919; UC5920; UC5921; UC5922; UC5925; UC5926; UC5933; UC5934; UC5940; UC5941; UC5968; UC5973; UC7568; UC7569; UC7570; UC7571; UC7575; UC7576; UC7577; UC7578; UC7582; UC7583; UC7584; UC7585; UC8936; UC8937; UC8938; UC8939; UC8983; UC8984; UC8985; UC8986; UC8992; UC8993; UE0009; UE0010; UE0011; UE0012; UE0016; UE0017; UE0018; UE0019; UF0026; UF0027; UF0028; UF0029; VF0089; VF0118; VF0119; VF0161; VF0162; VF0214; VF0215; VF0216; VF0217; VF0260; VF0261; VF0262; VF0263; VF0303; VF0321; VF0322

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Cefaclor	70356-03-5	4 - 13
Excipients	NA	87 - 96

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines:
Cefaclor - LEG <100 micrograms/m3 TWA for 12 hours.

Section 3 - Hazards Identification

Appearance: Free-flowing dry blend
Physical State: Solid
Odor: Strawberry

Emergency Overview

Special
A = Allergen

Emergency Overview Effective Date: 07-Apr-1999

Lilly Laboratory Labeling Codes:
Health 2 **Fire** 1 **Reactivity** 0 **Special** A

Primary Physical and Health Hazards: Irritant (eyes). Severe Allergen.

Caution Statement: Cefaclor for Oral Suspension may be irritating to the eyes and causes severe allergic reactions.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Eye irritation and allergic reactions to cefaclor have been reported. Based on prior experience with cephalosporin antibiotics, allergic reactions may include rash, nasal congestion, cough, dry throat, gastrointestinal upset, eye irritation, or anaphylactic shock.

Medical Conditions Aggravated by Exposure: Hypersensitivity to penicillin or cephalosporin.

Carcinogenicity: Cefaclor - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found
UEL: No applicable information found
LEL: No applicable information found

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

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic chloride fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

Section 7 - Handling and Storage

Storage Conditions: Controlled Room Temperature: 15 to 30 C (59 to 86 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin

contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Additional Exposure Precautions: In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

Section 9 - Physical and Chemical Properties

Appearance: Free-flowing dry blend
Odor: Strawberry
Boiling Point: No applicable information found
Melting Point: No applicable information found
Specific Gravity: No applicable information found
pH: 2.5-5.0 (reconstituted)
Evaporation Rate: No applicable information found
Water Solubility: Soluble
Vapor Density: No applicable information found
Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic chloride fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Toxicity data for the active ingredient, cefaclor, are presented.

Oral: Cefaclor - Rat, 5000 mg/kg, no deaths or toxicity.
Monkey, 1000 mg/kg, no deaths, diarrhea.

Skin: Cefaclor - Rabbit, 500 mg/kg, no deaths or toxicity.

Inhalation: Cefaclor - Rat, 224 mg/m3 for 1 hour, no deaths or toxicity.

Intraperitoneal: Cefaclor - Rat, median lethal dose 1259 mg/kg.

Skin Contact: Cefaclor - Rabbit, nonirritant

Eye Contact: Cefaclor - Rabbit, slight irritant

Chronic Exposure

Toxicity data for the active ingredient, cefaclor, are presented.

Target Organ Effects: Cefaclor - Kidney effects (dilation of renal tubules).

Other Effects: Cefaclor - Vomiting, soft stools, reversible thrombocytopenia.

Reproduction: Cefaclor - No effects identified in animal studies.

Sensitization: Cefaclor - Guinea pig, not a contact sensitizer.

Mutagenicity: No applicable information found.

Section 12 - Ecological Information

Ecotoxicity Data: Cefaclor
Daphnia magna 48-hour median effective concentration: > 916 mg/L
Green algae (S. capricornutum) median effective concentration: > 35 mg/L

Environmental Fate: Cefaclor
Dissociation constants (pKa): 2.43, 7.16
Log Kow: < 1 (pH 5)
Water solubility (g/L): 8.59 (pH 5)
Light absorption (nm): 264
Hydrolysis half-life (hrs): 406, 48, 13 (pH 5, 7, 9)
Hydrolysis rate (1/hrs): 0.00171, 0.0144, 0.0523, (pH 5, 7, 9)

Environmental Summary: Cefaclor - Practically nontoxic to aquatic invertebrates. Slightly toxic to green algae. No volatility expected. Low potential to bioconcentrate in aquatic organisms. Not persistent in water due to hydrolysis.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

Cefaclor
TSCA - No
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list
OSHA Substance Specific - No

EU Regulations

EC Classification
Xn (Harmful)
Xi (Irritant)

Risk Phrases
R 36 - Irritating to eyes.
R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases
S 25 - Avoid contact with eyes.
S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Section 16 - Other Information

MSDS Sections Revised: Section 1.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication

317-651-9533

For additional copies contact:
Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations

WEEL = Workplace Environmental Exposure Level (AIHA)