



Cephalexin Capsules and Tablets

Eli Lilly and Company
Material Safety Data Sheet

Effective Date: 19-Nov-1999

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: Cephalexin Capsules and Tablets

Chemical Name: 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(2R)-aminophenylacetyl]amino]-3-methyl-8-oxo-, monohydrate, (6R,7R)-

Chemical Name 2: 7-(D-alpha-Amino-alpha-phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid monohydrate

Synonym(s): Cephalexin M. F. Blend; Cephalexin; Cephalexin Monohydrate; Cephalexin Capsule Mix; Cephalexin Monohydrate Capsule Mix; 066873 Formulation; H69; H71; 4202; 4203; Cefalexina Capsules

Trademarks(s): Branfalexina; Kefalex; Falex; Keferol; Keflex Package; L-Keflex; Oref; Orakef; Kefloridina; Keflex KX; Keflex; Keforal

Lilly Item Code(s): AH0377; AH0378; CAP3001L; MS5062; MS5063; ND0711; ND0720; ND0730; ND0753; ND0762; ND0832; ND0833; ND0834; ND0861; ND0862; ND0868; ND0877; PU0401; PU0402; PU0403; PU3001; PU3069; PU3070; PU3140; PU3141; PU3246; QA432Z; QA433Y; QA455Z; QA476X; QD471R; TA1872; TA1894; TA1895; TA1896; TA4053; TA4090; TA4091; TA4202; TA4203; TA4210; TA4211; UC5010; UC5011; UC5346; UC5347; UC5348; UC5349; UC5376; UC5377; UC5930; UC5931; UC5938; UC5939; UC5942; UC5943; UC5944; UC5945; UC5961; UC5962; UC5970; UC5974; UC5975; UC5976; UC5977; UC5978; UC5979; UC8932; UC8933; UC8945; UC8946; UC9555; UC9556; UE0001; UE0002; UF0015; UF0016; UG9027; VF0072; VF0077; VF0079; VF0084; VF0085; VF0090; VF0092; VF0100; VF0101; VF0122; VF0142; VF0143; VF0155; VF0159; VF0160; VF0223; VF0224; VF0225; VF0226; VF0227; VF0254; VF0255; VF0256; VF0257; VF0264; VF0265; VF0273; VF0288; VF0289; VF0291; VF0292; VL0257

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

| Ingredient | CAS | Concentration % |
|------------------------|------------|------------------------|
| Cephalexin Monohydrate | 23325-78-2 | 14 - 96 |
| Excipients | NA | 4 - 85 |

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

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

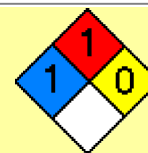
Section 3 - Hazards Identification

Appearance: White or colored powder finished as capsules or coated tablets

Physical State: Solid

Odor: Odorless

Emergency Overview



Special
A = Allergen

Emergency Overview Effective Date: 23-Apr-1994

Lilly Laboratory Labeling Codes:

Health 1

Fire 1

Reactivity 0

Special A

Primary Physical and Health Hazards: Not hazardous if intact. Severe Allergen.

Caution Statement: Intact Cephalexin Capsules and Tablets are not considered to be a health hazard. Cephalexin Capsules and Tablets contains cephalexin which causes severe allergic reactions.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Capsules and tablets are intended for human consumption under guidance of a physician. Capsules and tablets are not considered hazardous under normal handling procedures. Allergic reactions to cephalexin monohydrate have been reported. Allergic reactions to contents of capsules or to the powder used to make the tablets may include rash, nasal congestion, cough, dry throat, and eye irritation.

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

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

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

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: Not applicable

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 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.

Filled capsules and compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to contents may occur.

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: White or colored powder finished as capsules or coated tablets

Odor: Odorless

Boiling Point: Not applicable

Melting Point: No applicable information found

Specific Gravity: No applicable information found

pH: No applicable information found

Evaporation Rate: No applicable information found

Water Solubility: Slightly 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 fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

No data are available for Cephalexin Capsules and Tablets. Toxicity data for cephalexin monohydrate and cephalexin hydrochloride are presented.

Oral: Cephalexin monohydrate - Rat, 5000 mg/kg, no deaths, increased urine output, weight loss. Monkey, 1000 mg/kg, no deaths, diarrhea.

Skin: Cephalexin monohydrate - Rabbit, 153 mg/rabbit, no deaths or toxicity.

Inhalation: Cephalexin hydrochloride - Rat, 1990 mg/m³ for 4 hours, no deaths.

Intravenous: Cephalexin monohydrate - Rat, 700 mg/kg, no deaths or toxicity.
Dog, 100 mg/kg, no deaths, vomiting, tarry stools.

Skin Contact: Cephalexin monohydrate - Rabbit, nonirritant

Eye Contact: Cephalexin monohydrate - Rabbit, slight irritant

Chronic Exposure

No data are available for Cephalexin Capsules and Tablets. Toxicity data for cephalexin monohydrate are presented.

Target Organ Effects: Cephalexin monohydrate - No effects identified in animal studies.

Other Effects: Cephalexin monohydrate - Salivation and vomiting.

Reproduction: Cephalexin monohydrate - No effects identified in animal studies.

Sensitization: Cephalexin monohydrate - No applicable information found.

Mutagenicity: Cephalexin monohydrate - Not mutagenic in bacterial cells.

Section 12 - Ecological Information

No applicable ecological information found.

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

Cephalexin monohydrate

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

Contains cephalexin monohydrate (C = 14-96%)

Xn (Harmful)

Xi (Irritant)

Risk Phrases

R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases

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

317-277-6029

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)