Ceftazidime for Injection

Effective Date: 24-Feb-2001

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: Ceftazidime for Injection

Chemical Name: Pyridinium, 1-[[(6R,7R)-7-[[(2Z)-(2-amino-4-thiazolyl)[(1-carboxy-1-methylethoxy) imino]acetyl]amino]-2-carboxy-
8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-, inner salt, pentahydrate
Synonym(s): Ceftazidime; Ceftazidime Pentahydrate; Ceftazidime Buffered; Buffered Ceftazidime; 139381 Formulation
Trademarks(s): Ftazidime; Kefamin; Kefazim; Kefzim; Zidime; Zetadime; Tazidime; Kefadim; Seftaz
Lilly Item Code(s): CA1527; CA1528; CA1529; FS7245; FS7246; ID4026; ND0878; ND0879; ND0880; ND0885; ND0886; ND0887; ND0888; ND0928; ND0931; ND0933; QA290X; QA419W; QA442E; QA442V; QI0235; SI0138; SI0143; UC9506; UC9507; UC9508; UG9000; UG9001; UG9002; UG9003; UG9004; UG9005; UG9006; VF0188; VF0208; VF0209; VF0210; VF0274; VF0275; VF0276; VF0327; VF0328; VF0335; VL7230; VL7231; VL7234; VL7235; VL7238; VL7239; VL7241; VL7242; VL7290; VL7291; VL7292; VL7310; VL7311; VL7314; VL7318; VL7420; VL7421; VL7422; VL7423; VL7427; VL7460; VL7461; VL7462; VP7460; VP7461; VP7462

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Ceftazidime Pentahydrate	78439-06-2	88 - 90
Sodium Carbonate Monohydrate	5968-11-6	10 - 12

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

Exposure Guidelines:
Ceftazidime pentahydrate - LEG <100 micrograms/m3 TWA for 12 hours.
Sodium carbonate anhydrous - Exposure Guideline 500 micrograms/m3 TWA for 12 hours. (Lilly-established guideline)

Section 3 - Hazards Identification

Appearance: White to cream-colored crystalline powder
Physical State: Solid
Odor: Odorless

Emergency Overview

Special
A = Allergen

Emergency Overview Effective Date: 21-Nov-1998

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

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

Caution Statement: Ceftazidime for Injection may be irritating to the eyes and causes severe allergic reactions.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: None reported; however, based on prior experience with cephalosporin antibiotics, allergic reactions might be expected, including rash, nasal congestion, cough, dry throat, eye irritation, or anaphylactic shock. Dilute formulations of sodium carbonate may be irritating to the eyes.

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

Carcinogenicity: All ingredients - 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 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: Refrigerator: 2 to 8 C (36 to 46 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: White to cream-colored crystalline powder
Odor: Odorless
Boiling Point: No applicable information found
Melting Point: No applicable information found
Specific Gravity: No applicable information found
pH: 5.0-7.5 (10% aqueous)
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.) and strong acids.

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

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Data for the ingredients, ceftazidime pentahydrate and sodium carbonate, are presented where indicated.

Oral: Ceftazidime pentahydrate - Rat, 500 mg/kg, no deaths or toxicity.

Skin: Ceftazidime pentahydrate - Rabbit, 200 mg/kg, no deaths or toxicity.

Inhalation: Ceftazidime pentahydrate - Rat, 690 mg/m3 for 4 hours, no deaths.
Sodium carbonate anhydrous - Rat, median lethal concentration 2300 mg/m3 for 2 hours (approximately 4600 mg/m3 for 1 hour).

Intravenous: Ceftazidime pentahydrate - Rat, 2581 mg/kg, no deaths.
Monkey, 1500 mg/kg, no deaths, soft stools, diarrhea.

Skin Contact: Ceftazidime pentahydrate - Rabbit, nonirritant

Eye Contact: Ceftazidime pentahydrate - Rabbit, slight irritant
Sodium carbonate anhydrous - Rabbit, moderate to severe irritant
Rabbit, mild irritant (rinsed)

Chronic Exposure

Data for the active ingredient, ceftazidime pentahydrate, are reported.

Target Organ Effects: Ceftazidime pentahydrate - Blood effects (decreased red blood cell count, increased white blood cell count, decreased activated partial prothrombin time values), liver effects (increased liver weight), kidney effects (increased kidney weight, kidney tissue changes).

Other Effects: Ceftazidime pentahydrate - Salivation, vomiting, and soft or mucoid stools.

Reproduction: Ceftazidime pentahydrate - No effects identified in animal studies.

Sensitization: No applicable information found.

Mutagenicity: Ceftazidime pentahydrate - Not mutagenic in bacterial or mammalian cells.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

Ecotoxicity Data:
Sodium carbonate anhydrous
Bluegill 96-hour median lethal concentration: 300 to 320 mg/L
Fathead minnow 96-hour median lethal concentration: <850 mg/L
Daphnia magna 96-hour median lethal concentration: 265 to 565 mg/L

Environmental Fate: No applicable information found.

Environmental Summary:
Sodium carbonate anhydrous - Material is practically non-toxic to aquatic organisms. Material is soluble in water and is expected to leach from soil into groundwater

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

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

Remaining Ingredients
TSCA - Yes
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 ceftazidime pentahydrate (C = 88 to 90%)
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
317-277-6029

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)