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	Ceftriaxone for Injection, USP			Material Safety Data Sheet (MSDS)	
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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Ceftriaxone for Injection, USP

Product Code:
25021-105
25021-106
25021-107
25021-108

Common/Trade Name: Ceftriaxone for Injection, USP

Chemical Name: (6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-[[[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-*as*-triazin-3-yl)thio]methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7²-(Z)-(O-methyloxime), disodium salt, sesquaterhydrate

Chemical Family: Antibiotic

Product Use: Pharmaceutical

Product Type: Regulated Prescription Drug

Container Information: Glass vials

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Ceftriaxone sodium	100	104376-79-6


Section 3 - Hazards Identification

Primary Physical and Health Hazards: May cause eye and skin irritation. May cause allergic reaction.

Routes of Entry: Skin. Inhalation. Ingestion. Eye contact.

Signs & Symptoms of Exposure: Acute signs and symptoms of exposure may include eye, skin, and respiratory irritation. May cause nausea, vomiting, abdominal pain, headache, dizziness, light headedness, or skin rash.

Chemical Listed as Carcinogen: NTP: No IARC: No OSHA: No

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Medical Conditions Generally Aggravated by Exposure: Practically non-toxic if swallowed. Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Blood effects (may include increase in eosinophils, neutrophils, and platelets). Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Liver function effects (may include increased lever of SGOT, SGPT, serum LDH, jaundice). Renal function effects (may include increased level of creatinine, BUN, renal failure). Nervous system effects (headache, dizziness, light headedness).

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes or more. Seek medical attention if irritation or signs of exposure are noted.

Skin Exposure: Remove contaminated clothing, wash skin with water and soap for 15 minutes. Seek medical attention if irritation or signs of exposure are noted.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.

Injection: In cases of accidental injection, wash and disinfect area, seek medical attention.

Inhalation: If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures


Flash Point Not Applicable

Autoignition Temperature: Not Applicable

Flammable Limits in Air Lower %: Not Applicable
Upper %: Not Applicable

Flammable Limits: Not Applicable

Extinguishing Media Use foam or all purpose dry chemicals to extinguish.

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Special Fire Fighting Procedures:

As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

Unusual Fire/Explosion Hazards:

None.

Section 6 - Accidental Release Measures

Spill:

Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state or local regulations.

Release to Air:

If aerosolized, reduce exposures by ventilating area. Clean up immediately to prevent evaporation. Wear respiratory protection as necessary.

Release to Water:

Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling:


When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Waste Disposal Method:

Refer to local, state, and federal rules.

Storage Conditions:

Protect from light. Store powder at 20°-25°C (68°-77°F). [See USP Controlled Room Temperature]. Follow instructions provided in packaging.

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Section 8 - Exposure Controls / Personal Protection

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

Respiratory Protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR 1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode. Use chemical resistant, impervious gloves.

Eye Protection: Chemical goggles and/or face shield. Safety glasses are always required.

Ventilation: Handle product in a well ventilated area.


Skin Protection: Work uniform or laboratory coat.

Other Protective Equipment: Protective Latex or Nitrile gloves

Additional Exposure Precautions: Wash hands following use. No eating, drinking or smoking when handling this product.

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ceftriaxone	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

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Section 9 - Physical and Chemical Properties


Physical State:	Solid	Specific Gravity:	Not available
Appearance and Odor:	Crystalline powder. Light yellow to amber	Evaporation Rate:	Not available
Boiling Point:	Not available.	Melting Point:	Not available
Vapor Pressure:	Not available.	Solubility in Water:	Soluble
Vapor Density:	Not available.	pH:	6.7

Section 10 - Stability and Reactivity

Stability:	Stable under recommended storage conditions.
Incompatibility (Materials to avoid):	None identified
Hazardous Decomposition:	Not applicable.
Hazardous Polymerization:	Not applicable.
Conditions to Avoid:	Not applicable.

Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure:	IMMEDIATE EFFECTS: Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Blood effects (may include increase in eosinophils, neutrophils, and platelets). Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Liver function effects (may include increased level of SGOT, SGPT, serum LDH, jaundice). Renal function effects (may include increased level of creatinine, BUN, renal failure). Nervous system effects (headache, dizziness, and light headedness).
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Acute Toxicity

Component	Type	Route	Species	Dosage
Ceftriaxone sodium	LD ₅₀	Oral	Mouse	>10g/kg
Ceftriaxone sodium	LD ₅₀	Oral	Rat	>10 g/kg
Ceftriaxone sodium	LD ₅₀	Intravenous	Mouse	2.8 g/kg
Ceftriaxone sodium	LD ₅₀	Intravenous	Rat	2 g/kg
Ceftriaxone sodium	LD ₅₀	Intravenous	Rabbit	240 mg/kg

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 Sagent 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

TSCA - *Not on this list*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*


SARA 313 - *Not on this list*

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Section 16 - Other Information

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:
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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
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
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
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
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
NE	Not Established
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
OEL	Occupational Exposure Limit
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
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
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)