
	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 1 of 13


Section 1 - Identification

- (a) **Product Identifier:** Ceftazidime for Injection, USP
- (b) **Product Code:** 25021-127
25021-128
25021-129
- Common/Trade Name:** Ceftazidime
- Chemical Name:** Pyridinium, 1-[[7-[[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]-hydroxide, inner salt, [6R-6 α , 7 β (Z)]
- Chemical Family:** Antibiotic
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Glass vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618


Section 2 - Hazards Identification

- (a) **Classification:** **GHS Classifications**
- Skin irritation (Category 3)
 - Eye Irritation (Category 2A)
 - Respiratory Irritation (Category 1)
 - Skin sensitization (Category 1)
- HMIS Rating**
- | | |
|-----------------|---|
| Health Hazard | 2 |
| Flammability | 0 |
| Physical Hazard | 0 |
- NFPA Rating**
- | | |
|-------------------|---|
| Health Hazard | 2 |
| Fire Hazard | 0 |
| Reactivity Hazard | 0 |

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 2 of 13

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
	- <u>Signal Word</u> : Danger
<u>Hazard Statements:</u> H316 H317 H319 H334	- Causes mild skin irritation - May cause an allergic skin reaction - Causes serious eye irritation - May cause allergy or asthma symptoms or breathing difficulties if inhaled
<u>Precautionary Statements:</u> P261 P280 P305+ P351 + P338 P342 + P311 P362 + P364 P337 + P313 P304 + P341 P342 + P311 P302 + P352 P333 + P313 P403 + P233	- Avoid breathing dust/fumes/gas/mist/vapors/spray - Wear protective gloves - If in eyes, rinse cautiously with water for 15 minutes. Remove contacts if present and easy to do. Continue rinsing - If experiencing respiratory symptoms, call a Poison Center or doctor/physician - Take off contaminated clothing and wash it before reuse - If eye irritation persists, get medical advice/attention - IF INHALED : If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing - If experiencing respiratory symptoms, call a POISON CENTER or doctor/physician - IF ON SKIN : Wash with plenty of soap and water - If skin irritation or rash occurs, seek medical advice/attention - Store in a well-ventilated place. Keep container tightly closed

(d) Unknown Acute Toxicity: N/A


	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 3 of 13

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Pyridinium, 1-[[7-[[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]-hydroxide, inner salt, [6R-6 α , 7 β (Z)]	Ceftazidime Pentahydrate	88-90% (w/w)	78439-06-2	N/A
Sodium carbonate	Sodium Carbonate Monohydrate	10-12% (w/w)	5968-11-6	N/A

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.

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 4 of 13

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use water, carbon dioxide, foam, all purpose dry chemicals to extinguish or Halon.
- (b) **Hazardous Combustion Products:** May emit toxic fumes when exposed to heat or fire.
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

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.
- Storage Conditions:** No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Ceftazidime	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 5 of 13

(b) Engineering Controls


Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

Respiratory Protection:	Use an approved respirator.
Eye Protection:	Chemical goggles and/or face shield. Safety glasses are always required.
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.

Section 9 - Physical and Chemical Properties

(a)	Appearance	White to Cream-colored crystalline powder
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	5.0 – 7.5
(e)	Melting Point:	Not Applicable
(f)	Initial Boiling Point:	Not Available
(g)	Flash Point	Not Applicable
(h)	Evaporation Rate:	Not Available
(i)	Flammability	Not Applicable
(j)	Upper Lower Flammability or Explosion Limits	Not Applicable
(k)	Vapor Pressure:	Not Available
(l)	Vapor Density:	Not Available
(m)	Relative Density	Not Available
(n)	Solubility(ies)	Soluble in water

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 6 of 13


(o)	Partition Coefficient: n-octanol/water	Not Available
(p)	Auto-ignition Temperature	Not Applicable
(q)	Decomposition Temperature	Not Available
(r)	Viscosity	Not Available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable to normal temperatures and pressures.
(c)	Possibility of Hazardous Reactions	None
(d)	Conditions to Avoid	Not applicable.
(e)	Incompatible Materials	May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.) and strong acids.
(f)	Hazardous Decomposition Products	May emit toxic fumes when heated to decomposition.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin. Inhalation.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	May cause eye irritation. May cause allergic reaction.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	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.

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 7 of 13

(d) Acute Toxicity


Component	Type	Route	Species	Dosage
Ceftazidime pentahydrate	LD ₅₀	Oral	Rat	500 mg/kg
Ceftazidime pentahydrate	LD ₅₀	Skin	Rabbit	200 mg/kg
Ceftazidime pentahydrate	LD ₅₀	Inhalation	Rat	690 mg/m ³
Ceftazidime pentahydrate	LD ₅₀	Intravenous	Rat	2581 mg/kg
Ceftazidime pentahydrate	LD ₅₀	Intravenous	Monkey	1500 mg/kg
Ceftazidime pentahydrate	---	Skin Contact	Rabbit	Solution contact with skin
Ceftazidime pentahydrate	---	Eye Contact	Rabbit	Solution contact with eye
Sodium carbonate anhydrous	LD ₅₀	Inhalation	Rat	2300 mg/m ³
Sodium carbonate anhydrous	---	Eye Contact	Rabbit	Solution contact with eye

(e) Hazardous Chemical Listings

NTP: No


IARC: No

OSHA: No


	Sagent Pharmaceuticals, Inc.			
	Ceftazidime for Injection, USP		Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001

Section 12 - Ecological Information

(a)	Ecotoxicity	<p>This material contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.</p> <p>Activated Sludge Respiration This material contains an active ingredient that is not toxic to activated sludge microorganisms.</p> <p>IC50: > 103 mg/l, 3 Hours, Activated sludge, Nominal NOEC: 103 mg/l</p> <p>Microbial Growth Inhibition This material contains an active ingredient that is harmful to these microorganisms.</p> <p>Minimum Inhibition Concentration: 2 mg/l, , Pseudomonas, Measured</p> <p>Algal This material contains an active ingredient that is very toxic to algae. IC50: 0.025 mg/l, 72 Hours, Measured NOEC: 0.013 mg/l</p> <p>Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids. EC50: > 106 mg/l, 48 Hours, Daphnia magna, Measured NOEC: 106 mg/l</p>
	Ecotoxicity	

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 9 of 13

		<p>Fish This material contains an active ingredient that is not toxic to fish. EC50: > 106 mg/l, 96 Hours, Juvenile Oncorhynchus mykiss, rainbow trout, Measured NOEC: 106 mg/l</p>
(b)	Persistence and degradability	<p>Solubility This material contains an active ingredient that for environmental fate predictions has solubility in water.</p> <p>Partitioning This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.</p>
(c)	Bioaccumulative potential	<p>Hydrolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.</p> <p>Half-Life, Acidic: < 100 Hours, Measured Half-Life, Basic: < 1 Hours, Measured</p> <p>Biodegradation This material contains an active ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment. Cephalosporins are generally susceptible to degradation by a number of micro-organisms found in wastewater treatment plants and the general environment. Resulting degradation products are readily mineralised by environmental micro-organisms.</p> <p>Aerobic - Inherent Percent Degradation: 34 %, 14 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge</p>
(d)	Mobility in soil	<p>Adsorption This material contains an active ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This</p>

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 10 of 13

		material contains an active ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment. Soil Sediment Sorption (log Koc): 0.78, Measured at pH 7
(e)	Other Adverse Effects	No applicable ecological information found.


Section 13 - Disposal Considerations

Refer to local, state, and federal rules.

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

Section 14 - Transport Information

(a)	UN Number	UN3077 has a special provision in section 4.4 of the IATA under S.P. A197 that states: A197—is a new special provision assigned to environmentally substances, UN 3077 and UN 3082 that allows these substances to be shipped as “not restricted” provided that the net quantity in any receptacle does not exceed 5 kg or 5 L and the packaging used meets defined standards
(b)	UN Proper Shipping Name	Environmentally hazardous substance, solid, nos
(c)	Transport Hazard Class(es)	Not Restricted
(d)	Packing Group	III
(e)	Environmental Hazards	Per UN Model Regulation 5.2.1.6, may require environmentally hazardous substance mark (fish and tree symbol)
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 11 of 13

DOT:	Not Restricted
ICAO/IATA:	Not Restricted
IMDG:	Not Restricted

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
- OSHA – Possible Sensitizer, Target Organ Toxin, Possible Irritant
- RCRA – Not Listed
- PROP 65 – Not listed

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 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:
 Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
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 847-908-1600

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	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 12 of 13

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

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
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
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)

	Sagent Pharmaceuticals, Inc.				
	Ceftazidime for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Aug. 12, 2015	SDS No.: SDS 007	SDS Version No.: 4.0	Form No.: R-SOP-009-F001	Page: 13 of 13

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)
WHMIS	Workplace Hazardous Materials Information System