

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 1 of 11

Section 1 - Identification

- (a) **Product Identifier:** Cefazolin for Injection, USP
- (b) **Product Code:** 25021-100
25021-101
25021-102
- Common/Trade Name:** Cefazolin Sodium, Ancef for Injection
- Chemical Name:** 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]-methyl]-8-oxo-7-[[[(1H-tetrazol-1-yl)acetyl]amino]-, monosodium salt (6R-*trans*)
- Chemical Family:** semi-synthetic cephalosporin; antibacterial
- (c) **Product Use:** Antibiotic
- 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:** U.S. OSHA Classification
Possible sensitizer
Target Organ Toxin

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:		
<u>U.S. OSHA Classification</u>			
Hazard Categories	Category 1	Category 2	Category 1
Hazard Symbols			

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 2 of 11

Signal Words	Danger	Warning	Warning
Hazard Statements	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	May cause damage to the gastrointestinal system, liver, kidneys, blood, and skin through prolonged or repeated exposure.	May cause an allergic skin reaction.
Precautionary Statements:	<p>Avoid breathing dust/fume/gas/mist/vapors/spray. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves.</p> <p>IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/ attention.</p> <p>IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician</p>		

(d) **Unknown Acute Toxicity:** N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[[(5-methyl-1,3,4-thiazol-2-yl)thio]-methyl]-8-oxo-7-[[[(1H-tetrazol-1-yl)acetyl]amino]-, monosodium salt (6R- <i>trans</i>)	Cefazolin Sodium	100% by weight	27164-46-1	N/A

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 3 of 11

Section 4 - First Aid Measures

- Eye Exposure:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- 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

- (a) **Extinguishing Media** Water spray, dry chemical, or foam as appropriate. Carbon dioxide extinguishers may be ineffective.
- (b) **Hazardous Combustion Products:** When heated to decomposition it emits very toxic fumes of NO, Na₂O and SO.
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. No special requirements are needed for single units or packages. For larger amounts, self-contained breathing apparatus and protective equipment and clothing are recommended to minimize contact with respiratory tract, skin and eyes.

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 4 of 11

Section 6 - Accidental Release Measures

- Spill:** If a container breaks, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations. If a spill occurs after reconstitution, 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.
- 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:** No special control measures are required during the normal use of this product. During dispensing, avoid excessive aerosolization of the reconstituted product during dilution or transfers. When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. This material has not been tested for its dust explosion properties. However, like most organic dusts, it is expected to explode when ignited as a dust cloud. Care should be taken to avoid dispersion as a dust cloud.
- Storage Conditions:** No special storage required for hazard control. Before reconstitution, store at 20° to 25°C (68 to 77°F) and protect from light.
- Special Precautions:** None anticipated during the normal use of this product. Persons with known allergies to penicillins or other cephalosporins should consult a health or safety professional prior to handling this material.

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 5 of 11

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

(b) Engineering Controls

Ventilation: Laboratory fume hood or local exhaust ventilation.

(c) Individual Protection Measures

Respiratory Protection:	Respiratory protection is not needed during the normal use of this product. However, persons with known allergies to penicillins or other cephalosporins should consult their site health or safety professional regarding appropriate respiratory protection prior to handling this material.
Eye Protection:	Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Skin Protection:	If contact with unprotected skin is possible, the use of gloves is recommended. Persons with known allergies to penicillins or other cephalosporins should consult their site health or safety professional regarding appropriate selection of gloves prior to handling this material.
Other Protective Equipment:	No additional protective equipment known to be required.
Additional Exposure Precautions:	In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 6 of 11

Section 9 - Physical and Chemical Properties

(a)	Appearance	Solid white to off white lyophilized powder
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	4.5 – 6.0
(e)	Melting Point:	198 – 200°C
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Approx to water
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Approx to water
(n)	Solubility(ies)	Soluble in water, 0.9% sodium chloride, and in glucose solutions
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not available
(b)	Chemical Stability	Stable under recommended conditions
(c)	Possibility of Hazardous Reactions	Not determined; No hazardous polymerization anticipated to occur.
(d)	Conditions to Avoid	None identified

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 7 of 11

(e)	Incompatible Materials	Not determined. May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.). Cefazolin sodium is reported to be clinically incompatible with aminoglycosides.
(f)	Hazardous Decomposition Products	Not determined. During thermal decomposition, it may generate toxic fumes of carbon oxides, nitrogen oxides, sodium oxides and sulfur oxides.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	May be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Cefazolin Injection presents little hazard.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Severe Allergen. May cause irritation to eyes, skin, and respiratory tract. Product may cause allergic reaction if inhaled or absorbed through the skin. Hypersensitivity to penicillin or cephalosporin
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Exposure can cause dilation of the blood vessels and an increase in contraction of some smooth muscles.

(d) Acute Toxicity

Component	Percent	Type	Route	Species	Dosage
Cefazolin Sodium	100	LD ₅₀	IV	Rat	2760 mg/kg
Cefazolin Sodium	100	LD ₅₀	IV	Mouse	3900 mg/kg
Cefazolin Sodium	100	LD ₅₀	IV	Dog	2200 mg/kg
Cefazolin Sodium	100	LD ₅₀	IV	Rabbit	2500 mg/kg

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 8 of 11

Cefazolin Sodium	100	LD ₅₀	Oral	Rat	> 11,000 mg/kg
Cefazolin Sodium	100	LD ₅₀	Oral	Mouse	> 11,000 mg/kg

(e) Hazardous Chemical Listings

NTP: Not listed

IARC: Not listed

OSHA: Not listed

Section 12 - Ecological Information

(a)	Ecotoxicity	No applicable ecological information found.
(b)	Persistence and degradability	No applicable ecological information found.
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.

Section 13 - Disposal Considerations

If discarded as produced, this material is not a RCRA “listed” or “characteristic” hazardous waste. However, uses resulting in a chemical or physical change of the product, or contamination of the product with other materials may subject it to regulation as a hazardous waste. All waste materials must be properly characterized. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirement.

Section 14 - Transport Information

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available
(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.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 9 of 11

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMDG: 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 - Exempt

CERCLA - Not listed

SARA 302 - Not listed

SARA 313 - Not listed

California Proposition 65 – Not listed

RCRA Status – Not a hazardous waste

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

Schaumburg, IL 60195

847-908-1600

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	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 10 of 11

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
AICS	Australian Inventory of Chemical Substances
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
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
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
IMDG	International Maritime Dangerous Goods
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
NPDES	National Pollutant Discharge Elimination System
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

	Sagent Pharmaceuticals, Inc.				
	Cefazolin for Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 29, 2014	SDS No.: SDS 002	SDS Version No.: 6.0	Form No.: R-SOP-009-F001	Page: 11 of 11

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)
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