	Sagent Pharmaceuticals, Inc.			
	Cefazolin for Injection		Material Safety Data Sheet (MSDS)	
	Issue Date:	MSDS No.: MSDS 002	Version No.: 2.0	Form Number: R-SOP-009-F001

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: Cefazolin for Injection, USP (1gram, 10grams)
Product Code: NDC 25021-101-10
 NDC 25021-102-99
Common/Trade Name: Cefazolin Sodium
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: Cephalosporin antibiotic
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Glass Vials

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Cefazolin Sodium	100	None	None	None	27164-46-1


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Section 3 - Hazards Identification

Primary Physical and Health Hazards:	Severe Allergen. May cause irritation to eyes, skin, and respiratory tract. Product may cause allergic reaction if inhaled or absorbed through the skin.
Routes of Entry:	May be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Adenosine Injection presents little hazard.
Signs & Symptoms of Exposure:	Exposure can cause dilation of the blood vessels and an increase in contraction of some smooth muscles.
Chemical Listed as Carcinogen:	NTP: No IARC: No OSHA: No
Medical Conditions Generally Aggravated by Exposure:	Hypersensitivity to penicillin or cephalosporin

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.


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Section 5 - Fire Fighting Measures

Flash Point	Not determined
Autoignition Temperature:	Not available
Flammable Limits in Air	Lower %: Not available Upper %: Not available
Flammable Limits:	Not Applicable
Extinguishing Media	Water spray, dry chemical, or foam as appropriate. Carbon dioxide extinguishers may be ineffective.
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:	When heated to decomposition it emits very toxic fumes of NO, Na ₂ O and SO.

Section 6 - Accidental Release Measures

Spill:	Use the appropriate personal protective equipment, see Section 8. 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, and dispose according to local, state, and federal guidelines.
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.

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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. 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.
- Waste Disposal Method:** Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.
- Storage Conditions:** Protect from light and store at controlled room temperature 20°-25°C (68°-77°F). Follow instructions provided in packaging.

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:** If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
- Eye Protection:** Chemical goggles and/or face shield. Safety glasses are always required.
- Ventilation:** Laboratory fume hood or local exhaust ventilation.
- Skin Protection:** Work uniform or laboratory coat.
- Other Protective Equipment:** Protective Latex or Nitrile gloves
- Additional Exposure Precautions:** In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

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Exposure Limits


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

Section 9 - Physical and Chemical Properties

Physical State:	Solid	Specific Gravity:	Approx to water
Appearance and Odor:	White to off white lyophilized power, no Odor	Evaporation Rate:	Approx to water
Boiling Point:	Not available	Solubility in Water:	Soluble
Vapor Pressure:	Not available	pH:	4.5-6.0 (10% solution)
Vapor Density:	Not available	Molecular Weight:	476.5

Section 10 - Stability and Reactivity

Stability:	Stable at normal temperature and pressures.
Incompatibility (Materials to avoid):	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.
Conditions to Avoid:	None identified

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Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure:

IMMEDIATE EFFECTS:

Eye, skin and respiratory irritation may occur. Classified as a non-irritant to rabbit skin. No signs of irritation occurred after 3 minute, 1 hour or up to 3 days after direct application in rabbits for four hours. Classified as a mild irritant in rabbit eyes. Signs of irritation, such as redness or swelling occurred after direct application in rabbits. Eyes appeared normal after 7 days.

DELAYED EFFECTS:

Hypersensitivity reactions ranging from mild to life-threatening may occur.

Acute Toxicity


Component	Type	Route	Species	Dosage
Cefazolin Sodium	LD ₅₀	IV	Rat	2760 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.

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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 - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*


OSHA Substance Specific - *No*

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:

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

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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)