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Section 1 - Identification

- (a) **Product Identifier:** Cefoxitin for Injection, USP
- (b) **Product Code:** 25021-109, 25021-110, 25021-111
- Common/Trade Name:** Mefoxin, Cefoxitin for Injection, USP
- Chemical Name:** Sodium (6R,7S)-3-(hydroxymethyl)-7-methoxy-8-oxo-7-[2-(2-thienyl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate carbamate (ester)
- Chemical Family:** Antibiotic
- (c) **Product Use:** Anti-infective
- Product Type:** Regulated Prescription Drug
- Container Information:** 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:**

HMIS Rating


Health Hazard	0
Flammability	0
Physical Hazard	0

NFPA Rating

Health Hazard	0
Fire Hazard	0
Reactivity Hazard	0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<p>- <u>GHS Label elements, including precautionary statements:</u> Not a hazardous substance or mixture</p>	

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


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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Sodium (6R,7S)-3-(hydroxymethyl)-7-methoxy-8-oxo-7-[2-(2-thienyl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate carbamate (ester)	Cefoxitin Sodium	100% (w/w)	33564-30-6	N/A

Section 4 - First Aid Measures

- Eye Exposure:** If this product comes in contact with the eyes, wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
- Skin Exposure:** If skin contact occurs, immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
- Ingestion:** If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

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Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
- (b) **Hazardous Combustion Products:** Carbon oxides, Nitrogen oxides, Sulphur oxides, Sodium oxides
- (c) **Special Protective Equipment / Precautions:** Wear self-containing breathing apparatus and protective clothing.

Section 6 - Accidental Release Measures

- Spill:** Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
- Release to Air:** Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.
- 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. 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:** Store at between 2°-25°C (36°-77°F). Avoid temperatures above 50°C. Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limit

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

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(b) Engineering Controls

Ventilation: General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

(c) Individual Protection Measures

Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required. Enclosed local exhaust ventilation is required at points of dust, fume, or vapor generation.
Eye Protection:	Safety glasses or goggles recommended.
Skin Protection:	Disposable latex gloves are recommended. For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers
Other Protective Equipment:	For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
Additional Exposure Precautions:	Not Available

Section 9 - Physical and Chemical Properties

(a) Appearance	White to off-white powder
(b) Odor	Slight characteristic odor
(c) Odor Threshold	Not available
(d) pH	4.2 – 7.0
(e) Melting Point:	149-150°C (decomposes)
(f) Initial Boiling Point:	Not available
(g) Flash Point	Not established
(h) Evaporation Rate:	Approx to water
(i) Flammability	Not established
(j) Upper Lower Flammability or Explosion Limits	Not established

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(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	>1
(m)	Relative Density	Approx to water
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not established
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	No data available
(b)	Chemical Stability	Stable
(c)	Possibility of Hazardous Reactions	No hazardous polymerization
(d)	Conditions to Avoid	Avoid direct sunlight and conditions that might generate heat and dispersion as dust cloud.
(e)	Incompatible Materials	Oxidizing agents
(f)	Hazardous Decomposition Products	When heated to decomposition material emits toxic fumes of NO _x (nitrogen oxides) and SO _x (Sulfur oxides)

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses include: allergic reactions, hypotension, gastrointestinal neuromuscular, renal, and hepatic abnormalities. Occupational exposure has not been fully investigated.

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(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	<p>IMMEDIATE EFFECTS: Eye, skin, and respiratory irritation may occur. Exposure may cause allergic reactions in certain individuals and cross-allergenicity with penicillin-allergic individuals.</p> <p>DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.</p>
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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Cefoxitin Sodium	LD ₅₀	Oral	Rat	>10 gm/kg
Cefoxitin Sodium	LD ₅₀	Oral	Mouse	>10 gm/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

Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.


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Section 14 - Transport Information

(a)	UN Number	UN 3077
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	III
(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

DOT:

Symbols	G
Hazard class or Division	9
Identification Numbers	UN3077
PG	III
Label Codes	9
Special Provisions	8, 146, 335, B54, IB8, IP3, N20, T1, TP33
Packaging: Exceptions	155
Packaging: Non-bulk	213
Quantity limitations (Passenger aircraft/rail)	No limit
Quantity limitations (Cargo aircraft only)	No limits
Vessel stowage (Location)	A
Vessel stowage (Other)	None

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IATA:

ICAO/IATA Class	9
ICAO/IATA Subrisk	None
UN/ID Number	3077
Packing Group	III
Special Provisions	A97
Cargo Only	
Packing Instructions	956
Maximum Qty/Pack	400 kg
Passenger and Cargo	
Packing Instructions	956
Maximum Qty/Pack	400 kg
Passenger and Cargo Limited Quantity	
Packing Instructions	Y956
Maximum Qty/Pack	30 kg G

IMDG:

IMDG	9
IMDG Subrisk	None
UN Number	3077
Packing Group	III
EMS Number	F-A, S-F
Special Provisions	274 335
Limited Quantities	5 kg
Marine Pollutant	Yes


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
 SARA 311/312 – Chronic Health Hazard
 OSHA Substance Specific - No

Massachusetts Right to Know Components – None
 Pennsylvania Right to Know Components – CAS No. 33564-30-6
 New Jersey Right to Know Components – CAS No. 33564-30-6

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California Prop 65 Components – This product does not contain any chemicals known to cause cancer, birth defects, or any other reproductive harm

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

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

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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
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