	Sagent Pharmaceuticals, Inc.				
	Cefepime 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: Cefepime for Injection, USP
Product Code: 25021-121 (1 gram)
 25021-122 (2 gram)
Common/Trade Name: Cefepime Hydrochloride
Chemical Formula C₁₉H₂₄N₆O₅S₂
Chemical Family: Cephalosporin
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vial

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Cefepime Hydrochloride	62	123171-59-5
L-arginine	38	74-79-3


Section 3 - Hazards Identification

Primary Physical and Health Hazards: May cause irritation to eyes, skin, and respiratory tract.

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, Cefepime for Injection presents little hazard.

Signs & Symptoms of Exposure: Acute signs and symptoms of exposure may include eye, skin, and respiratory irritation.

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

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Medical Conditions Allergies, Colitis, Kidney Disorders
Generally Aggravated by Exposure:

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 if any symptoms appear.

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 Water spray or multi-purpose ABC extinguisher.

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.

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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: Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.


Storage Conditions: Protect from light, avoid excessive heat, sparks or flames. 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: Under normal use, respirators should not be required if adequate ventilation is available. A dust/mist respirator (N95) may be necessary if aerosols are generated.

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

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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>
Cefepime Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Solid	Specific Gravity:	Not Established
Appearance and Odor:	White to Off-White Powder	Evaporation Rate:	Not Established
Boiling Point:	Not available	Melting Point:	Not applicable
Vapor Pressure:	1.26 x 10 ⁻⁷ Torr	Solubility in Water:	Soluble
Vapor Density:	Not Available	pH:	2.4 – 4.5 (0.25g/l)
		Molecular Weight	480.56

Section 10 - Stability and Reactivity


Stability: Stable at normal temperature and pressures.

Incompatibility (Materials to avoid): None identified

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.

Acute Toxicity

Component	Type	Route	Species	Dosage
Cefepime for Injection	LD ₅₀	IV	Mouse	1500 - 2000 mg/kg
	LD ₅₀	Oral	Rat	1,272 mg/kg
	LD ₅₀	IV	Dog	> 2000 mg/kg

Section 12 - Ecological Information

Acute Toxicity to Aquatic Invertebrates

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Incineration at an approved, permitted facility is recommended.


Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

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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*

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)