

1. PRODUCT AND COMPANY INFORMATION

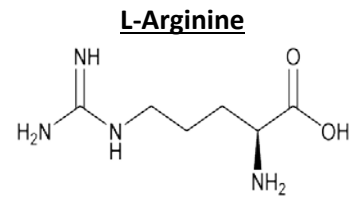
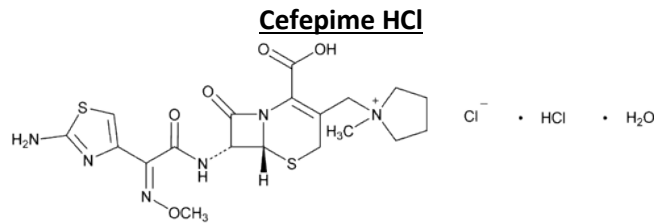
Distributed By: WG Critical Care, LLC.
120 Route 17 North
Suite 115
Paramus, NJ 07652 USA

Product Name: **Cefepime for Injection, USP**

Active

Ingredient/Primary Component: Cefepime for Injection, USP

Structure:



Chemical Name:

Cefepime HCl

(1) Pyrrolidinium, 1-[[[7-[[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methyl-, chloride, monohydrochloride, monohydrate, [6R-[6 α ,7 β (Z)]]-; (2) 1-[[[(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methylpyrrolidinium chloride, 7²-(Z)-(O-methyloxime), monohydrochloride, monohydrate

L-Arginine
L-Arginine

Molecular Formula:

Cefepime HCl
 $C_{19}H_{25}ClN_6O_5S_2 \cdot HCl \cdot H_2O$

L-Arginine
 $C_6H_{14}N_4O_2$

UNII Code:

Cefepime HCl
UNII-18X100607P

L-Arginine
UNII-94ZLA3W45F

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1. PRODUCT AND COMPANY INFORMATION (CONT.)

CAS Number:	<u>Cefepime HCl</u> 123171-59-5	<u>L-Arginine</u> 74-79-3
Chemical Family:	<u>Cefepime HCl</u> Antibacterial	<u>L-Arginine</u> Ammonia detoxicant; diagnostic aid (pituitary function determination)
Product Use:	Pharmaceutical	
Product Type:	Prescription Drug	
Container Information:	Vials	
Customer Service Phone Number:	+1-888-493-0861	
Emergency Phone Number:	+1-866-562-4708 (Prosar)	

2. HAZARDS IDENTIFICATION

PRIMARY PHYSICAL AND HEALTH HAZARDS:	May cause respiratory tract, eye, and skin irritation. May cause allergic respiratory and skin reaction		
ROUTES OF ENTRY:	Eye, Skin, Inhalation, Ingestion		
SIGNS & SYMPTOMS OF EXPOSURE:	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: local reactions, rash, diarrhea, nausea, vomiting, pruritus, positive Coombs' test, and other laboratory changes. Occupational exposure has not been fully investigated.		
CHEMICAL LISTED AS CARCINOGEN:	NTP: NO	IARC: NO	OSHA: NO

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS Number</u>
Cefepime HCl	58%	123171-59-5
L-Arginine	42%	74-79-3

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4. FIRST AID MEASURES

EYE EXPOSURE:	Rinse opened eye for several minutes under running water. If symptoms persist, seek medical attention.
SKIN EXPOSURE:	Immediately wash with water and soap and rinse thoroughly. If symptoms persist seek medical attention.
INGESTION:	Do NOT induce vomiting. Flush mouth out with water and seek medical attention.
INHALATION:	Seek medical attention.
NOTE TO PHYSICIAN:	Please see patient package insert.

5. FIRE FIGHTING MEASURES

FLASH POINT:	Not established
AUTO-IGNITION TEMPERATURE:	Not established
FLAMMABLE LIMITS IN AIR:	Not established
FLAMMABLE LIMITS:	Not established
EXTINGUISHING MEDIA:	CO ₂ , ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
UNUSUAL FIRE / EXPLOSION HAZARDS:	Emits toxic fumes of carbon monoxide, carbon dioxide, hydrogen chloride, oxides of nitrogen, and sulfur oxides.

6. ACCIDENTAL RELEASE MEASURE

SPILL:	Contain and collect spillage and place in container for disposal according to local regulations (See Section 13). Wipe surface area clean with soap and water. Avoid contact with strong oxidizing agents.
RELEASE TO AIR:	Prevent release to drains and waterways. Prevent release to the environment.
RELEASE TO WATER:	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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:	Store at 2° - 25°C (36° - 77°F). Protect from light

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION:	If respiratory protection is used, the type of protection will depend upon air concentration present, required protection factor as well as hazards, physical properties of substance.
EYE PROTECTION:	Safety glasses with side shields or goggles are recommended.
VENTILATION:	General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.
SKIN PROTECTION:	Protect with disposable garments if direct skin contact is anticipated.
OTHER PROTECTIVE EQUIPMENT:	Chemical resistant gloves.
ADDITIONAL EXPOSURE PRECAUTIONS:	Wash hands and face before breaks and immediately after handling product.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Solid	SPECIFIC GRAVITY:	Not established
APPEARANCE AND ODOR:	White; Can range from white to pale yellow in solution	EVAPORATION RATE:	Not established
BOILING POINT:	Not established	MELTING POINT:	Not established
VAPOR PRESSURE:	1.26×10^{-7} Torr	SOLUBILITY:	Freely soluble in water
VAPOR DENSITY:	Not established	pH:	4.0-6.0
Percent Volatile:	Not established	Explosive Properties:	Not established

10. STABILITY AND REACTIVITY

STABILITY:	Stable when stored under conditions outlined in section 7.
HAZARDOUS POLYMERIZATION:	Does not occur
CONDITIONS TO AVOID:	Protect from light

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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Cefepime HCl	LD ₅₀	IV	Rat	1067 mg/kg
Cefepime HCl	LD ₅₀	IV	Mouse	1500-2000mg/kg
Cefepime HCl	LD ₅₀	IV	Dog	2000 mg/kg

12. ECOLOGICAL INFORMATION

No applicable information found.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

IMO: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TSCA – No

CERCLA-No

SARA 313 – No

OSHA Substance Specific - No

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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.

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