

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

Product Code: 1g Vial: 44567-240-10

2g Vial: 44567-241-10

Common/Trade Name: Cefepime for Injection, USP

Structure: <u>Cefepime HCl</u>

Chemical

Cefepime HCl L-Arginine

L-Arginine

L- Arginine

 $\bar{N}H_2$

NH

Name: (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, [6*R*-

 $\label{eq:continuous} \begin{array}{ll} [6\alpha,7\beta(\textit{Z})]]_{-;} & (2) \ 1-[[(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methylpyrrolidinium chloride, 7^2-(\textit{Z})-(\textit{O}-thiazolyl)glyoxylamido]-1-methylpyrrolidinium chloride, 7^2-(\textit{D}-thiazolyl)glyoxylamido]-1-methylpyrrolidinium chloride, 7^2-(\textit{D}-thiazolyl)glyoxylamido]-1-methylpyrrolidinium chloride, 7^2-(\textit{D}-thiazolyl)glyoxylam$

methyloxime), monohydrochloride, monohydrate

MolecularCefepime HClL-ArginineFormula: $C_{19}H_{25}CIN_6O_5S_2.HCl\cdot H_2O$ $C_6H_{14}N_4O_2$

UNII Code: <u>Cefepime HCl</u> <u>L-Arginine</u>

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1. PRODUCT AND COMPANY INFORMATION (CONT.)

CAS Number: <u>Cefepime HCl</u> <u>L-Arginine</u>

123171-59-5 74-79-3

Chemical Cefepime HCl L-Arginine

Family: Antibacterial Ammonia detoxicant;

diagnostic aid (pituitary function determination)

Product Use: Pharmaceutical Product Type: Prescription Drug

Container Information: Vials

General Phone Number: +1-847-549-3200 **Customer Service Phone Number:** +1-888-493-0861

Emergency Phone Number: +1-866-562-4708 (Prosar)

2. COMPOSITION / INFORMATION ON INGREDIENTS

 Ingredient
 Weight %
 CAS Number

 Cefepime HCl
 58%
 123171-59-5

 L-Arginine
 42%
 74-79-3

3. HAZARDS INDENTIFICATION

PRIMARY PHYSICAL AND HEALTH May cause respiratory tract, eye, and skin irritation. May cause

HAZARDS: allergic respiratory and skin reaction

ROUTES OF ENTRY: Eye, Skin, Inhalation, Ingestion

EXPOSURE: 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

Potential adverse reactions from prescribed doses and overdoses

exposure has not been fully investigated.

CHEMICAL LISTED AS

SIGNS & SYMPTOMS OF

CARCINOGEN:

NTP: NO IARC: NO OSHA: NO

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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:

AUTO-IGNITION TEMPERATURE:

FLAMMABLE LIMITS IN AIR:

Not established

Not established

Not established

EXTINGUISHING MEDIA: CO2, 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 Wash hands and face before breaks and immediately after

PRECAUTIONS: handling product.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: Solid SPECIFIC GRAVITY: Not established APPEARANCE AND White to pale yellow EVAPORATION RATE: Not established

ODOR: powder / No odor

BOILING POINT: Not established **MELTING POINT:** Not established

VAPOR PRESSURE: 1.26 x 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 MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). 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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