



## SAFETY DATA SHEET

**Product Name: MAXIPIME™ (Cefepime Hydrochloride, USP) for Injection**

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
<b>Emergency Telephone</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000
<b>Product Name</b>	MAXIPIME™ (Cefepime Hydrochloride, USP) for Injection
<b>Synonyms</b>	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 $\alpha$ -(Z)-(O-methyloxime), monohydrochloride, monohydrate.

### 2. HAZARD(S) IDENTIFICATION

<b>Emergency Overview</b>	MAXIPIME™ (Cefepime Hydrochloride, USP) for Injection is a powder containing arginine and cefepime hydrochloride, a semi-synthetic, broad spectrum, antibacterial agent belonging to the cephalosporin class of antibacterials. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potential sensitizer. The reconstituted product is not anticipated to be irritating. Persons known to be allergic to penicillins or other cephalosporins should take precautions when handling this material. Based on clinical use, possible target organs may include the gastrointestinal system, skin, blood, liver, and kidneys.
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#### U.S. OSHA GHS Classification

<b>Physical Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified
<b>Health Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Eye Damage/Irritation	2B
	Sensitization – Skin	1
	Sensitization – Respiratory	1
	STOT - RE	2

#### **Label Element(s)**

**Pictogram**



**Signal Word**

Danger

**Hazard Statement(s)**

Causes eye irritation  
May cause an allergic skin reaction  
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled  
May cause damage to organs through prolonged or repeated exposure.

**2. HAZARD(S) IDENTIFICATION: continued**

**Precautionary Statement(s)**

**Prevention**

Do not breathe dust/vapors/spray  
 In case of inadequate ventilation, wear respiratory protection  
 Wear protective gloves  
 Wash hands thoroughly after handling  
 Contaminated work clothing must not be allowed out of the workplace

**Response**

Get medical attention if you feel unwell.  
 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.  
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Active Ingredient Name</b>	Cefepime Hydrochloride Hydrate	L-Arginine
<b>Chemical Formula</b>	C <sub>19</sub> H <sub>25</sub> ClN <sub>6</sub> O <sub>5</sub> S <sub>2</sub> • HCl • H <sub>2</sub> O	C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub>

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Cefepime Hydrochloride Hydrate	62	123171-59-5	NA
L-Arginine	38	74-79-3	CF1934200

**4. FIRST AID MEASURES**

**Eye Contact**

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact**

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation**

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion**

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

**Flammability**

None anticipated for this product. However, many organic powders will combust at elevated temperatures.

**Fire & Explosion Hazard**

None anticipated for this product. Avoid the creation of dusty environments.

**Extinguishing Media**

As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

**Special Fire Fighting Procedures**

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

**6. ACCIDENTAL RELEASE MEASURES**

**Spill Cleanup and Disposal** If a container breaks, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, 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.

**7. HANDLING AND STORAGE**

**Handling** No special handling required for hazard control under conditions of normal product use.

**Storage** No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** No special precautions required for hazard control. Persons with known allergies to penicillins or other cephalosporins should consult a health or safety professional prior to handling open containers of this material.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Cefepime Hydrochloride Hydrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
L-Arginine	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

**Respiratory Protection** Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin Protection** If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye Protection** Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls** Engineering controls are normally not needed during the normal use of this product.

## 9. PHYSICAL/CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	A sterile, dry mixture of cefepime hydrochloride and L-arginine
<b>Odor</b>	NA
<b>Odor Threshold</b>	NA
<b>pH</b>	The pH of the reconstituted solution is 4.0 to 6.0
<b>Melting point/Freezing Point</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Flash Point</b>	NA
<b>Evaporation Rate</b>	NA
<b>Flammability (solid, gas)</b>	NA
<b>Upper/Lower Flammability or Explosive Limits</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Relative Density</b>	NA
<b>Solubility</b>	NA
<b>Partition Coefficient: n-octanol/water</b>	NA
<b>Auto-ignition Temperature</b>	NA
<b>Decomposition Temperature</b>	NA
<b>Viscosity</b>	NA

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to Avoid</b>	Not determined
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sulfur oxides (SOx), and hydrogen chloride.
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity** - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
*Cefepime:L-Arginine	62:38	LD50	Intravenous	1500-2000 1272 >2000	mg/kg mg/kg mg/kg	Mouse Rat Dog

LD 50: Dosage that produces 50% mortality.

\* BMS MSDS for Maxipime for Injection

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Occupational Exposure Potential</b>	Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust and liquid aerosol generation and skin contact.
<b>Signs and Symptoms</b>	None anticipated from normal handling of this product. Based on clinical use of this product in patients, following an accidental occupational exposure, possible adverse effects may include gastrointestinal upset (nausea, vomiting, stomach cramps, loss of appetite), headache, dizziness, elevated liver enzymes, elevated kidney enzyme levels, and altered hematological parameters (anemia, neutropenia, thrombocytopenia). Persons allergic to penicillins or other cephalosporin antibiotics may experience allergic reactions including fever, rash, itching, difficulty breathing, or anaphylaxis.
<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/ Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/ Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. As a class, cephalosporin antibiotics are sensitizers in studies in animals. Allergic reactions have also been reported in patients during the clinical use of this product. Persons with known allergies to penicillins or cephalosporin antibiotics should use care when handling open containers of this material.
<b>Reproductive Effects</b>	None anticipated from normal handling of this product. No untoward effects on fertility were noted in rats given cefepime subcutaneously at dosages up to 1000 mg/kg/day. Cefepime was not teratogenic or embryocidal when administered during the period of organogenesis to rats at dosages up to 1000 mg/kg/day or to mice at dosages up to 1200 mg/kg or to rabbits at a dosage level of 100 mg/kg.
<b>Mutagenicity</b>	In chromosomal aberration studies, cefepime was positive for clastogenicity in primary human lymphocytes, but negative in Chinese hamster ovary cells. In other <i>in vitro</i> assays (bacterial and mammalian cell mutation, DNA repair in primary rat hepatocytes, and sister chromatid exchange in human lymphocytes), cefepime was negative for genotoxic effects. Moreover, <i>in vivo</i> assessments of cefepime in mice (2 chromosomal aberration and 2 micronucleus studies) were negative for clastogenicity.
<b>Carcinogenicity</b>	The carcinogenic potential of cefepime has not been fully evaluated.
<b>Carcinogen Lists</b>	<b>IARC:</b> Not listed <b>NTP:</b> Not listed <b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs may include the gastrointestinal system, skin, blood, liver, and kidneys.

**12. ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity**</b>	Not determined for product. For Cefepime L-Arginine: EC50 (Daphnia magna (Water flea) = 640 mg/l (study was conducted on a different salt form).
<b>Persistence/Biodegradability</b>	Not determined for product.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

\*\*BMS MSDS for Maxipime for Injection

Notes: 1. EC50: Concentration in water that produces 50% inhibition of growth in algae.

**13. DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

**14. TRANSPORTATION INFORMATION**

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

**15. REGULATORY INFORMATION**

<b>US TSCA Status</b>	Exempt
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**GHS/CLP Classification\***      \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

<b>Hazard Class</b>	<b>Hazard Category</b>	<b>Pictogram</b>	<b>Signal Word</b>	<b>Hazard Statement</b>
NA	NA	NA	NA	NA

**Prevention**

Do not breathe dust/vapors/spray  
 In case of inadequate ventilation, wear respiratory protection  
 Wear protective gloves  
 Wash hands thoroughly after handling  
 Contaminated work clothing must not be allowed out of the workplace

**15. REGULATORY INFORMATION: continued**

<b>GHS/CLP Classification:</b>	continued
<b>Response</b>	Get medical attention if you feel unwell.  IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.  IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.  Collect spillage. Avoid release into the environment
<b><u>EU Classification*</u></b>	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
<b>Classification(s)</b>	NA
<b>Symbol</b>	NA
<b>Indication of Danger</b>	NA
<b>Risk Phrases</b>	R42/43: May cause sensitization by inhalation and skin contact
<b>Safety Phrases</b>	S22: Do not breath dust S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection. S61: Avoid release into the environment

**16. OTHER INFORMATION**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD <sub>50</sub>	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

**16. OTHER INFORMATION:** continued

MSDS Coordinator: Hospira GEHS  
Date Prepared: July 23, 2012  
Date(s) Revised: June 02, 2014

**Disclaimer:**

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