



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 1 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

Product Form: Mixture

Product Name: Cefepime for Injection, USP

### 1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Medical Treatment: Antibiotics

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
224-443-4617  
[www.meithealpharma.com](http://www.meithealpharma.com)

### 1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Resp. Sens. 1 H334

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

### 2.2. Label Elements

#### GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) : Danger

Hazard Statements (GHS-US) :

H317 - May cause an allergic skin reaction.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May form combustible dust concentrations in air

Precautionary Statements (GHS-US) :

P261 - Avoid breathing vapors, mist, or spray.  
P272 - Contaminated work clothing must not be allowed out of the workplace.  
P280 - Wear protective gloves, protective clothing, and eye protection.  
P284 - [In case of inadequate ventilation] wear respiratory protection.  
P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.  
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.  
P302+P352 - If on skin: Wash with plenty of soap and water.  
P333+P313- If skin irritation or rash occurs: Get medical advice/attention.  
P362 - Take off contaminated clothing and wash before reuse.

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 2 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

### 2.3. Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Cefepime Hydrochloride Hydrate	(CAS-No.) 123171-59-5	62	Resp Sens. 1 (H334) Skin Sens. 1 (H317)
Arginine	(CAS-No.) 74-79-3	38	Not listed

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures After Inhalation:** Remove exposed person to fresh air. Refer to a physician if subject experiences difficulty breathing. If breathing has stopped, a trained person should perform cardiopulmonary resuscitation (CPR) and seek immediate medical assistance.

**First-aid Measures After Skin Contact:** Wash skin with soap and water. If skin irritation persists, call a physician.

**First-aid Measures After Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**First-aid Measures After Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2- Hazards Identification and/or Section 11-Toxicological Information.

**Medical Conditions Aggravated by Exposure:** Allergies to cephalosporin antibiotics. People allergic to penicillins may exhibit cross reaction sensitivity.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Explosion Hazard:** Fine particles (such as dust and mists) may fuel fires/explosions.

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 3 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

### 5.3. Advice for Firefighters

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including self-contained breathing apparatus.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### 6.2. Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 6.3. Methods and Materials for Containment and Cleaning Up

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

**Methods for Cleaning Up:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

### 7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions.  
Medical Treatment: Antibiotics.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters



For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

Appropriate Engineering Controls : Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

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SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 4 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

Personal Protective Equipment	: Gloves. Protective clothing. Protective goggles.
	  
Materials for Protective Clothing	: Chemically resistant materials and fabrics.
Hand Protection	: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations.
Eye and Face Protection	: Wear safety glasses or goggles if eye contact is possible
Skin and Body Protection	: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory Protection	: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter).
Other Information	: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Powder
Appearance	: White to pale yellow powder
Odor	: None
Odor Threshold	: No data available
pH	: 4-6 after reconstitution
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
<b>Flammability (solid, gas)</b>	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
<b>Solubility</b>	: Soluble in water
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
Viscosity	: No data available

**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** No data available.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 5 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

- 10.3. **Possibility of Hazardous Reactions:** None.
- 10.4. **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- 10.5. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur, hydrogen chloride and other chlorine- and sulfur-containing compounds.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Short Term:** Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. Allergic reaction might occur following inhalation of dust, based on effects of other cephalosporins. Symptoms might include running nose, sneezing, itching, pulmonary obstruction or signs similar to asthma such as coughing, wheezing or difficulty breathing which may be immediate or delayed.

**Known Clinical Effects:** Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. The most common side effect seen during clinical use is skin rash. Gastrointestinal effects such as diarrhea, nausea and vomiting also occur frequently following oral administration

**Acute Toxicity:**

<b>Cefepime Hydrochloride Hydrate (123171-59-5)</b>	
LD50 Intravenous Rat	1272 mg/kg
LD50 IV Mouse	1500-2000 mg/kg
<b>Arginine (74-79-3)</b>	
LD50 Oral Rat	>5110 mg/kg

**Skin Corrosion/Irritation:** Arginine :Non-irritating (Rabbit)

**Serious Eye Damage/Irritation:** Arginine : Non-irritating (Rabbit)

**Respiratory or Skin Sensitization:** Arginine :Non-irritating (Rabbit)

**Repeated Dose Toxicity (Duration, Species, Route, End Point, Target Organ):**

<b>Cefepime Hydrochloride Hydrate (123171-59-5)</b>					
28 Days	Rat	Subcutaneous	500 mg/kg/day	NOAEL	Blood

**Carcinogenicity:** Not classified

**Genetic Toxicity (Study Type, Cell Type/Organism, Result):**

<b>Cefepime Hydrochloride Hydrate (123171-59-5)</b>		
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Chromosome Aberration	Mouse	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative

<b>Arginine (74-79-3)</b>		
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 6 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

**Reproductive and Development Toxicity (Duration, Species, Route, Dose, End Point, Effect(s)):**

Cefepime Hydrochloride Hydrate (123171-59-5)					
Reproductive & Fertility	Rat	Subcutaneous	1000 mg/kg/day	NOAEL	No effects at maximum dose
Embryo/Fetal Development	Rat	Subcutaneous	1000 mg/kg/day	NOAEL	Not Teratogenic
Embryo/Fetal Development	Rabbit	No route specified	100 mg/kg/day	NOAEL	Not Teratogenic
Embryo/Fetal Development	Mouse	No route specified	1200 mg/kg/day	NOAEL	Not Teratogenic

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity**

**Aquatic Toxicity:**

Cefepime Hydrochloride Hydrate (123171-59-5)	
EC50 <i>Daphnia magna</i>	640 mg/L
Arginine (74-79-3)	
LC50 <i>Brachydanio rerio</i> (Zebra fish)	2800 mg/L (Exposure time: 96 hours)
Method: OECD	
EC50 <i>Daphnia magna</i> (Water Flea)	1800 mg/L (Exposure time: 24 hours)
Method: OECD	

**12.2. Persistence and Degradability**

**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

Arginine (74-79-3)	
OECD Activated Sludge Ready	100% After 28 Days Ready

**12.3. Bioaccumulative Potential**

**Partition Coefficient: (Method, pH, Endpoint, Value)**

Arginine (74-79-3)	
Measured 7 Log P	-4.2

**12.4. Mobility in Soil** No information available

**12.5. Other Adverse Effects**

Other Information : Avoid release to the environment.

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1. Waste Treatment Methods**

**Waste Disposal Recommendations:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Cefepime for Injection USP Safety Data Sheet	SDS Number: SDS-000011	Page Number: Page 7 of 7
Function: Regulatory Affairs	Effective Date: December 04, 2018	Version Number: 1.0

#### SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

- 14.1. **In Accordance with DOT** Not regulated for transport
- 14.2. **In Accordance with IMDG** Not regulated for transport
- 14.3. **In Accordance with IATA** Not regulated for transport

#### SECTION 15: REGULATORY INFORMATION

##### 15.1. US Federal Regulations

<b>Arginine (74-79-3)</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
Inventory-United States TSCA-Sect. 8(b)	Present

<b>Cefepime Hydrochloride Hydrate (123171-59-5)</b>	
CERCLA/SARA 313 Emission reporting	Not Listed

##### 15.2. US State Regulations

<b>Arginine (74-79-3)</b>	
California Proposition 65	Not Listed

<b>Cefepime Hydrochloride Hydrate (123171-59-5)</b>	
California Proposition 65	Not Listed

#### SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 12/04/2018  
 Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

##### GHS Full Text Phrases:

Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

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