

Safety Data Sheet

CEFEPIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/13/2015

1. Identification

1.1. Product identifier

Product Identity

CEFEPIME FOR INJECTION USP AND DEXTROSE INJECTION USP

Alternate Names

Catalog No: 3193-11, 3195-11

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use

Antibacterial

Application Method

See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name

B. Braun Medical Inc.

2525 McGaw Ave

Irvine, CA 92614

Emergency

(800) 854-6851

Customer Service: B. Braun Medical Inc.

(949) 660-2000

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Eye Dam. 1;H318

Causes serious eye damage.

Skin Sens. 1;H317

May cause an allergic skin reaction.

Resp. Sens. 1;H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.



Danger

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

[Prevention]:

P261 Avoid breathing dust / fume / gas / mist / vapors / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves / eye protection / face protection.

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P285 In case of inadequate ventilation wear respiratory protection.

[Response]:

P302+352 IF ON SKIN: Wash with plenty of soap and water.

P304+341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.

P310 Immediately call a POISON CENTER or doctor / physician.

P313 Get medical advice / attention.

P321 Specific treatment (see information on this label).

P333+313 If skin irritation or a rash occurs: Get medical advice / attention.

P342+311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

P363 Wash contaminated clothing before reuse.

[Storage]:

No GHS storage statements

[Disposal]:

P501 Dispose of contents / container in accordance with local / national regulations.

3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
L-Arginine CAS Number: 0000074-79-3	50 - 75	Not Classified	[1]
Cefepime Hydrochloride CAS Number: 0123171-59-5	50 - 75	Skin Sens. 1;H317 Eye Dam. 1;H318 Resp. Sens. 1;H334	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

This SDS and its hazards pertain to the drug component only - the diluent is a nonhazardous mixture of dextrose and water.

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4. First aid measures

4.1. Description of first aid measures

General	Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.
Inhalation	Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.
Eyes	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
Ingestion	If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Overview	Acute Symptoms: Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Chronic Symptoms: Possible hyper sensitization, antibiotic-associated pseudo membranous colitis, and super infections. Inhalation: May cause irritation. Eye: Causes severe irritation. Avoid contact. Skin: May cause irritation. Ingestion: May cause irritation. Adverse Effects: Adverse effects of Cephalosporins may include nausea; vomiting; taste alteration; decrease salivation; heartburn; decrease appetite; severe abdominal cramps, tenderness, or pain; diarrhea; which may be watery, bloody or severe; fever; unusual bruising or bleeding; sore mouth or tongue; and anal or genital itching. Drinking alcohol or using alcohol-containing preparations while exposed to this material may cause abdominal cramps, nausea, vomiting, headache, weakness, and flushing. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose Effects: Overdose effects may include confusion, hallucinations, stupor, coma, involuntary movement, and seizures. Overdose Treatment: Treatment should be symptomatic and supportive and may include: 1. Administer activated charcoal as a slurry. 2. For hypersensitivity reactions, manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine. 3. For seizures, administer intravenous diazepam or lorazepam. If seizure recur, consider phenobarbital. 4. For dysrhythmias, treat with standard antiarrhythmic drugs, if necessary. 5. Monitor fluid and electrolyte status in patients with severe vomiting and/or diarrhea. Monitor renal and hematologic abnormalities. 6. For coagulopathies, administer vitamin K. 7. For mild pseudomembranous colitis, treatment is usually NOT necessary. For moderate to severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an oral antibacterial drug effective against <i>Clostridium difficile</i>. 8. Hemodialysis may aid in elimination of cefepime. [Meditext 2006 and PDR 2006]
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Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, history of bleeding disorders, kidney or liver function impairment, gall bladder disease, gastrointestinal disease, and colitis.

Cross Sensitivity: Persons sensitive to one cephalosporin or cephamycin, or to penicillins, penicillin derivatives, or penicillamine may be sensitive to this material also..

See section 2 for further details.

Inhalation

May cause allergy or asthma symptoms of breathing difficulties if inhaled.

Eyes

Causes serious eye damage.

Skin

May cause an allergic skin reaction.

5. Fire-fighting measures

5.1. Extinguishing media

Water spray, dry chemical, carbon dioxide or foams as appropriate for surrounding fire and materials.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Emits toxic fumes of carbon dioxide, carbon monoxide, hydrogen chloride, nitrogen oxides and sulfur oxides.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

ERG Guide No.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear approved respiratory protection, chemically compatible gloves and protective clothing.

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site with plenty of water.

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7. Handling and storage

7.1. Precautions for safe handling

As a general rule, when handling this product avoid all contact and inhalation of dust and/or vapor. Wash thoroughly after handling.

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Store per label instructions to ensure product integrity.

Incompatible materials: No data available.

See section 2 for further details. - [Storage]:

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0000074-79-3	L-ARGININE	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0123171-59-5	Cefepime Hydrochloride	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0000074-79-3	L-ARGININE	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0123171-59-5	Cefepime Hydrochloride	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

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8.2. Exposure controls

Respiratory	When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.
Eyes	Safety Glasses.
Skin	Protect exposed skin. Rubber (use non-latex gloves if possible).
Engineering Controls	No special ventilation required.
Other Work Practices	Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

9. Physical and chemical properties

Appearance	White to Pale Yellow Powder
Odor	Odorless
Odor threshold	Not Measured
pH	Not Measured
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure	1.26×10^{-7} Torr
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Freely Soluble
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

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10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid exposure to light and heat.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Emits toxic fumes of carbon dioxide, carbon monoxide, hydrogen chloride, chloride, nitrogen oxides and sulfur oxides.

11. Toxicological information

Acute toxicity

Cefepime

IV Female Rat: LD50: 1067 mg/Kg

IV Mouse: LD50: 1500 to 2000 mg/kg

IV Dog: LD50: 2000 mg/kg

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
L-ARGININE - (74-79-3)	No data available	No data available	No data available	No data available	No data available
Cefepime Hydrochloride - (123171-59-5)	No data available	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Mutagenicity Data:

A battery of in vivo and in vitro genetic toxicity tests, including the Ames Salmonella reverse mutation assay, CHO/HGPRT mammalian cell forward gene mutation assay, chromosomal aberration and sister chromatid exchange assays in human lymphocytes, CHO fibroblast clastogenesis assay, and cytogenic and micronucleus assays in mice, were conducted and provided no evidence of genotoxic potential

Reproductive and Developmental Effects:

No impairment of fertility was observed in rats given cefepime at doses up to 1000 mg/kg/day during pregnancy. Cefepime did not cause birth defects or adverse effects to the fetus when administered during pregnancy to rats at doses up to 1000 mg/kg/day, to mice at doses up to 1200 mg/kg/day, or to rabbits at a dose level of 100 mg/kg/day.

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Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	1	Causes serious eye damage.
Respiratory sensitization	1	May cause allergy or asthma symptoms of breathing difficulties if inhaled.
Skin sensitization	1	May cause an allergic skin reaction.
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
L-ARGININE - (74-79-3)	Not Available	Not Available	Not Available
Cefepime Hydrochloride - (123171-59-5)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

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13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user	No further information		

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	D2A E
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): Yes Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

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Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Pennsylvania RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

16. Other information

The information provided in this SDS is intended to be used in the handling of this material in the work place. This SDS is not a substitute for the direction for use of product literature that may accompany the finished product. All information contained in this SDS has been assembled from other published documents and are assumed to be accurate. In the event of an adverse incident associated with this material, this SDS is not intended to be a substitute for consultation with appropriately qualified personnel.

The full text of the phrases appearing in section 3 is:

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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