

# Safety Data Sheet

## CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

### 1. Identification

#### 1.1. Product identifier

**Product Identity**

CEFTAZIDIME FOR INJECTION USP AND  
DEXTROSE INJECTION USP

**Alternate Names**

Catalog No: 3143-11, 3145-11

#### 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 Irrit. 2;H319

Causes serious eye irritation.

Skin Sens. 1;H317

May cause an allergic skin reaction.

Resp. Sens. 1;H334

May cause allergy or asthma symptoms of 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.

H319 Causes serious eye irritation.

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

**[Prevention]:**

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

# Safety Data Sheet

## CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

P264 Wash thoroughly after handling.

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

P280 Wear protective gloves / eye protection / face protection.

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.

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.

P337+313 If eye irritation persists: 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
Ceftazidime Pentahydrate CAS Number: 0078439-06-2	75 - 100	Resp. Sens. 1;H334 Skin Sens. 1;H317	[1]
Sodium carbonate CAS Number: 0000497-19-8	10 - 25	Eye Irrit. 2;H319	[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.

## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

#### 4. First aid measures

##### 4.1. Description of first aid measures

<b>General</b>	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.
<b>Inhalation</b>	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.
<b>Eyes</b>	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
<b>Skin</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
<b>Ingestion</b>	If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

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

<b>Overview</b>	<p><b>Acute Symptoms:</b> Possible eye, skin, gastrointestinal and/or respiratory tract irritation.</p> <p><b>Chronic Symptoms:</b> Possible hyper sensitization and superinfection.</p> <p><b>Inhalation:</b> May cause irritation.</p> <p><b>Eye:</b> May cause irritation. Avoid contact.</p> <p><b>Skin:</b> May cause irritation and contact dermatitis.</p> <p><b>Ingestion:</b> May cause irritation.</p> <p><b>Adverse Effects:</b> Adverse effects of Cephalosporins may include black, tarry stool; chest pain; cough; fever; painful or difficult urination; shortness of breath; sore throat; sore ulcers, or white spots on lips or in mouth; swollen glands; unusual bleeding or bruising; skin itching, rash or redness; hives or welts; abdominal or stomach pain and cramps; nausea; vomiting; diarrhea, which may be watery, bloody, or severe; headache; indigestion; flatulence; unusual tiredness or weakness; loss of appetite; headaches, dizziness and vaginal itching or discharge. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.</p> <p><b>Overdose Effects:</b> Not Found.</p> <p><b>Overdose Treatment:</b> Treatment of cephalosporin overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. For hypersensitivity reactions, manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. For dysrhythmias, treat with standard antiarrhythmic drugs, if necessary. Monitor fluid and electrolyte status in patients with severe vomiting and/or diarrhea. Monitor renal and hematologic abnormalities. For coagulopathies, administer vitamin K. For mild pseudo membranous colitis, treatment is usually NOT necessary. For moderate to severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an oral antibacterials drug effective against <i>Colstridium difficile</i>.</p> <p><b>Medical Conditions Aggravated by Exposure:</b> Hypersensitivity to material, active alcoholism, history of bleeding disorders, kidney or liver function impairment, porphyria, concurrent potent diuretic treatment, and gastrointestinal disease, especially ulcerative</p>
-----------------	--

## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

colitis, regional enteritis, or antibiotic-associated 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 irritation.

**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: When heated to decomposition material emits toxic fumes of NO<sub>x</sub>, SO<sub>x</sub>, HCl, and Cl<sub>2</sub>.  
Emits toxic fumes under fire conditions.

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.

# Safety Data Sheet

## CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

### 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
0000497-19-8	Sodium carbonate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0078439-06-2	Ceftazidime Pentahydrate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

The exposure limits for nuisance dust are: OSHA PEL: 15 mg/m<sup>3</sup> (50 mppcf\*) TWA, ACGIH 10 mg/m<sup>3</sup>.

##### Carcinogen Data

CAS No.	Ingredient	Source	Value
0000497-19-8	Sodium carbonate	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;
0078439-06-2	Ceftazidime Pentahydrate	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;

## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

#### 8.2. Exposure controls

<b>Respiratory</b>	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.
<b>Eyes</b>	Safety Glasses.
<b>Skin</b>	Protect exposed skin. Rubber (use non-latex gloves if possible).
<b>Engineering Controls</b>	Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.
<b>Other Work Practices</b>	No special ventilation required. 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

<b>Appearance</b>	White to pale yellow Powder
<b>Odor</b>	Unknown
<b>Odor threshold</b>	Not Measured
<b>pH</b>	Not Measured
<b>Melting point / freezing point</b>	Not Measured
<b>Initial boiling point and boiling range</b>	Not Measured
<b>Flash Point</b>	Not Measured
<b>Evaporation rate (Ether = 1)</b>	Not Measured
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Upper/lower flammability or explosive limits</b>	<b>Lower Explosive Limit:</b> Not Measured <b>Upper Explosive Limit:</b> Not Measured
<b>Vapor pressure (Pa)</b>	0.000000126 Torr
<b>Vapor Density</b>	Not Measured
<b>Specific Gravity</b>	Not Measured
<b>Solubility in Water</b>	Freely Soluble.
<b>Partition coefficient n-octanol/water (Log Kow)</b>	Not Measured
<b>Auto-ignition temperature</b>	Not Measured
<b>Decomposition temperature</b>	Not Measured
<b>Viscosity (cSt)</b>	Not Measured

#### 9.2. Other information

No other relevant information.

## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

#### 10. Stability and reactivity

##### 10.1. Reactivity

Hazardous Polymerization will not occur.

##### 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

When heated to decomposition material emits toxic fumes of NO<sub>x</sub>, SO<sub>x</sub>, HCl, and Cl<sub>2</sub>. Emits toxic fumes under fire conditions.

#### 11. Toxicological information

##### Acute toxicity

Ceftazidime Pentahydrate IV Mouse LD50: 6300 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
Ceftazidime Pentahydrate - (78439-06-2)	>20,000.00, Rat - Category: NA	No data available	No data available	No data available	No data available
Sodium carbonate - (497-19-8)	4,090.00, Rat - Category: 5	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).

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	2	Causes serious eye irritation.
Respiratory sensitization	1	May cause allergy or asthma symptoms of breathing difficulties if inhaled.

## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

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
Ceftazidime Pentahydrate - (78439-06-2)	Not Available	Not Available	Not Available
Sodium carbonate - (497-19-8)	300.00, Lepomis macrochirus	265.00, Daphnia magna	242.00 (72 hr), Freshwater Algae

### 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.

## 13. Disposal considerations

### 13.1. Waste treatment methods

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



## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

#### 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

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

**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.

## Safety Data Sheet

### CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date:

05/12/2015

**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.

H319 Causes serious eye irritation.

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.**

End of Document