Safety Data Sheet  
CEFOXITIN FOR INJECTION  
SDS Revision Date: 05/13/2015

1. Identification

1.1. Product identifier
Product Identity  
CEFOXITIN FOR INJECTION
Alternate Names  
Catalog No: 3123-11, 3125-11

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
Skin Sens. 1; H317  
May cause an allergic skin reaction.

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

Warning
H317 May cause an allergic skin reaction.

[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.
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.

<table>
<thead>
<tr>
<th>Ingredient/Chemical Designations</th>
<th>Weight %</th>
<th>GHS Classification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thiencylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate</td>
<td>50 - 75</td>
<td>Skin Sens. 1;H317</td>
<td>[1]</td>
</tr>
<tr>
<td>Cefoxitin</td>
<td>50 - 75</td>
<td>Not Classified</td>
<td>[1]</td>
</tr>
</tbody>
</table>

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.

*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.

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:** May cause irritation.

**Skin:** May cause irritation.

**Ingestion:** May cause irritation.

**Adverse Effects:** Adverse effects of Cephalosporins may include black, tarry stool; chest pain; chills; cough; fever; painful or difficult urination; shortness of breath; sore throat; sores; ulcers; or white spots on lips or in mouths; swollen glands; unusual bleeding or bruising; unusual tiredness or weakness; dizziness; nausea; vomiting; heartburn; severe abdominal cramps, tenderness, or pain; diarrhea, which may be watery, bloody or severe; unusual bruising or bleeding; sore mouth or tongue; and anal or genital itching. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** Not Found.

**Overdose Treatment:** Treatment of overdose should be symptomatic and supportive and may include:

- For acute hypersensitivity- Administer the usual agents (antihistamines, corticosteroids, or epinephrine, or other pressor amines), oxygen and airway management, including intubation.

- For antibiotic-associated pseudomembranous colitis- Moderate to severe cases may require fluid, electrolyte and protein replacement. Oral doses of metronidazole, bacitracin, chloestramine, or vancomycin may be used repeat as necessary. Do NOT use antiperistaltic antidiarrheals for severe watery diarrhea.

- Administer anticonvulsants if clinically indicated. (USP DI 2003)

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material, active alcoholism, history of bleeding disorders, kidney function impairment and gastrointestinal disease, especially ulcerative colitis, regional enteritis, or antibiotic-associated colitis.

**Cross Sensitivity:** Individuals sensitive to penicillin, penicillin derivatives, penicillamine, other cephalosporins, or cephamycin may be sensitive to this material also.

**Pregnancy Concerns:** Adequate and well-controlled pregnancy studies in humans have not been done. Studies in mice and rats given parenteral doses up to 7.5 times the human dose have not shown evidence of fetal harm. See section 2 for further details.

**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 NOx, SOx. 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.

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: Incompatible with oxidizing agents.

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

7.3. Specific end use(s)

Usual Adult Dose: Cefoxitin for Injection is administered by intravenous infusion; typical doses range from 1 to 2 grams (Cefoxitin) every 4, 6 or 8 hours (must be prescribed by physicians)
8. Exposure controls and personal protection

8.1. Control parameters

8.1.1. Exposure

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0033564-30-6</td>
<td>Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid</td>
<td>OSHA</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACGIH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIOSH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
<tr>
<td>0035607-66-0</td>
<td>Cefoxitin</td>
<td>OSHA</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACGIH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIOSH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
</tbody>
</table>

8.1.2. Carcinogen Data

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0033564-30-6</td>
<td>Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid</td>
<td>OSHA</td>
<td>Select Carcinogen: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NTP</td>
<td>Known: No; Suspected: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IARC</td>
<td>Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;</td>
</tr>
<tr>
<td>0035607-66-0</td>
<td>Cefoxitin</td>
<td>OSHA</td>
<td>Select Carcinogen: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NTP</td>
<td>Known: No; Suspected: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IARC</td>
<td>Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;</td>
</tr>
</tbody>
</table>

8.2. Exposure controls

8.2.1. Respiratory

When working with small quantities in a well-ventilated area, respiratory protection may not be required. The DUPLEX® container is designed to be used after the powder is constituted with the dextrose diluent. If for some reason, large powder spill occurs (multiple units breakage), the use of an approved dust mask is recommended to be worn before cleaning up the spill.

8.2.2. Eyes

Safety Glasses.

8.2.3. Skin

Protect exposed skin. Rubber (use non-latex gloves if possible).

8.2.4. Engineering Controls

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.

8.2.5. Other Work Practices

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>White to Off White Crystalline Powder</td>
</tr>
<tr>
<td>Odor</td>
<td>Unknown</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not Measured</td>
</tr>
<tr>
<td>pH</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>149-150°C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Evaporation rate (Ether = 1)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td><strong>Lower Explosive Limit</strong>: Not Measured</td>
</tr>
<tr>
<td></td>
<td><strong>Upper Explosive Limit</strong>: Not Measured</td>
</tr>
<tr>
<td>Vapor pressure (Pa)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Freely Soluble</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Kow)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Viscosity (cSt)</td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>9.2. Other information</strong></td>
<td>No other relevant information.</td>
</tr>
</tbody>
</table>

### 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**
Incompatible with oxidizing agents.

**10.6. Hazardous decomposition products**
When heated to decomposition material emits toxic fumes of NOx, SOx. Emits toxic fumes under fire conditions.

11. Toxicological information

Acute toxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Oral LD50, mg/kg</th>
<th>Skin LD50, mg/kg</th>
<th>Inhalation Vapor LC50, mg/L/4hr</th>
<th>Inhalation Dust/Mist LC50, mg/L/4hr</th>
<th>Inhalation Gas LC50, ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-ca - (33564-30-6)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Cefoxitin - (35607-66-0)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>1</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
12. Ecological information

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

Aquatic Ecotoxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>96 hr LC50 fish, mg/l</th>
<th>48 hr EC50 crustacea, mg/l</th>
<th>ErC50 algae, mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-ca - (33564-30-6)</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Cefoxitin - (35607-66-0)</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

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.

14. Transport information

14.1. UN number
Not Applicable

14.2. UN proper shipping name
Not Regulated

14.3. Transport hazard class(es)
DOT Hazard Class: Not Applicable

14.4. Packing group
DOT (Domestic Surface Transportation) Not Applicable

IMO / IMDG (Ocean Transportation) Not Regulated

ICAO/IATA Not Regulated

Air Class: Not Applicable

Page 8 of 10
14.5. Environmental hazards
IMDG
Marine Pollutant: No
14.6. Special precautions for user
No further information

15. Regulatory information

<table>
<thead>
<tr>
<th>Regulatory Overview</th>
<th>The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxic Substance Control Act (TSCA)</td>
<td>All components of this material are either listed or exempt from listing on the TSCA Inventory.</td>
</tr>
<tr>
<td>WHMIS Classification</td>
<td>D2B</td>
</tr>
</tbody>
</table>
| 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.

**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 form other published document 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.

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