1. Identification

1.1. Product identifier
Product Identity: CEFOTETAN FOR INJECTION AND DEXTROSE INJECTION
Alternate Names: Catalog No: 3173-11, 3175-11

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.
Resp. Sens. 1;H334: May cause allergy or asthmatic 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.
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.
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.
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.

<table>
<thead>
<tr>
<th>Ingredient/Chemical Designations</th>
<th>Weight %</th>
<th>GHS Classification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefotetan Disodium</td>
<td>100</td>
<td>Skin Sens. 1;H317 Resp. Sens. 1;H334</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.
Safety Data Sheet
CEFOTETAN FOR INJECTION AND DEXTROSE INJECTION

SDS Revision Date: 05/13/2015

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 and superinfection.

Inhalation: May cause irritation.
Eye: May cause irritation.
Skin: May cause irritation.

Ingestion: May cause irritation.

Adverse Effects: Adverse effects of Cephalosporins may include mild or severe diarrhea; abdominal cramps; sores, ulcers, or white spots on lips or in mouth; black, tarry stools; chest pain; chills, cough; painful or difficult urinations; shortness of breath; sore throat; swollen glands; unusual tiredness or weakness; nausea or vomiting; headache; unusual bleeding or bruising; sore mouth or tongue; fever; rash or hives; and vaginal itching or discharge. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Acute overdose of cephalosporins may result in nausea, vomiting, diarrhea, or abdominal pain.

Overdose Treatment: Treatment of cefotetan overdose should be symptomatic and supportive and may include the following:
Serious acute hypersensitivity reactions may require epinephrine or other pressor amines, antihistamines or corticosteroids, as well as anticonvulsants for seizures if needed.
Severe diarrhea may be treated with fluid, electrolyte, and protein replacement.
Administration of antiperistaltic antidiarrheals is NOT recommended; oral vancomycin, metronidazole, bacitracin, or chlolestyramine should be used instead.
Cefotetan is removed by hemodialysis [USP DI 2006]

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism or recent alcohol ingestion, history of bleeding disorders, impaired kidney function, carnitine deficiency, and history of colitis or gastrointestinal disease.

Cross Sensitivity: Persons sensitive to any cephalosporin or cephamycin, or to any penicillin, 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.

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.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe 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
Spill Response: 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 a detergent solution containing dilute sodium hydroxide.

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: Cefotetan for Injection, after constitution with Dextrose Injection, is administered by intravenous infusion; doses range from 1 to 2 grams (Cefotetan) every 12 hours, not to exceed 6 grams per day. This product cannot be used without prescription. Consult product insert for more information.
8. Exposure controls and personal protection

8.1. Control parameters

Exposure

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0069712-56-7</td>
<td>Cefotetan Disodium</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>

Carcinogen Data

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0069712-56-7</td>
<td>Cefotetan Disodium</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

Respiratory
Use a NIOSH-approved respirator, if it is determined necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Eyes
Safety Glasses.

Skin
Protect exposed skin. Chemically compatible gloves are recommended.

Engineering Controls
Engineering controls such as exhaust ventilation are recommended.

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

Appearance
White to pale yellow Clumpy powder.

Odor
Unknown

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
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>Cefotetan Disodium - (69712-56-7)</td>
<td>10,000.00, Rat -</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).
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>Cefotetan Disodium - (69712-56-7)</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

<table>
<thead>
<tr>
<th>DOT (Domestic Surface Transportation)</th>
<th>IMO / IMDG (Ocean Transportation)</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN number</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>UN proper shipping name</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>DOT Hazard Class: Not Applicable</td>
<td>IMDG: Not Applicable</td>
</tr>
<tr>
<td>Packing group</td>
<td>Not Applicable</td>
<td>Sub Class: Not Applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Air Class: Not Applicable</td>
</tr>
</tbody>
</table>

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

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.
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