Safety Data Sheet
CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP

SDS Revision Date: **05/13/2015**

1. Identification

1.1. Product identifier

Product Identity	CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP
Alternate Names	Catalog No: 3201-11, 3103-11, 3105-11

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 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.

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.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
SODIUM (6R-TRANS)-3-[[(5-METHYL-1,3,4-THIADIAZOL-2 **CAS Number: 0027164-46-1**	**100**	**Skin Sens. 1;H317** **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.

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. Not Defined

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 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:** Allergic reactions might be expected, including rash, nasal congestion, cough, dry throat, eye irritation or anaphylactic shock. **Overdose Treatment:** Treatment is 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 pseudo membranous colitis- Moderate to severe cases may require fluid, electrolyte and protein replacement. Oral doses of metronidazole, bacitracin, cholestyramine, or vancomycin may be usedl repeat as necessary. Do NOT use antiperistaltic antidiarrheals for severe watery diarrhea. -Administer anticonvulsants if clinically indicated (USP DI 20th ed 2000) **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; however, studies in animals at doses up to 25 times the human dose have not shown that cefazolin causes adverse effects on the fetus or impaired fertility. 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. 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: No data available.

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

7.3. Specific end use(s)

Usual Adult Dose: Cefazolin is administered by intravenous infusion; doses range from 250 mg to 1.5 grams every 6 to 12 hours, not to exceed 6 grams per day.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0027164-46-1	SODIUM (6R-TRANS)-3-[[(5-METHYL-1,3,4-THIADIAZOL-2	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0027164-46-1	SODIUM (6R-TRANS)-3-[[(5-METHYL-1,3,4-THIADIAZOL-2	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;

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 off-white Crystalline or 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 (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	0.4%
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.

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. Emits toxic fumes under fire conditions.

11. Toxicological information

Acute toxicity

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
SODIUM (6R-TRANS)-3-[[(5-METHYL-1,3,4-THIADIAZOL-2 - (27164-46-1)	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).

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	---	Not Applicable
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
SODIUM (6R-TRANS)-3-[[(5-METHYL-1,3,4-THIADIAZOL-2 - (27164-46-1)	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.

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

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.

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