

SAFETY DATA SHEET

Issue Date: 2/28/2024

Revision Date: N/A

Revision Number: 01

1. IDENTIFICATION

Product identifier: Cefotan (Cefotetan for Injection, USP)

NDC Numbers:

Distributor Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 2960

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – antibiotic

Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

| Physical | Health |
|---------------|---|
| Not hazardous | Skin Sensitization Category 1 Respiratory Sensitization Category 1 |

Label Elements:
Danger!



Hazard statement(s)

May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement(s)

Avoid breathing dust.
Contaminated clothing must not be allowed out of the workplace.
Wear protective clothing and gloves.

Precautionary statement(s)

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.
In case of inadequate ventilation, wear respiratory protection.
IF INHALED: remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical name | CAS No. | Amount |
|--------------------|------------|--------|
| Cefotetan Disodium | 74356-00-6 | 100% |

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation or rash develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Repeated skin contact may cause an allergic skin reaction. Inhalation of dust may cause an allergic respiratory reaction with asthma symptoms (wheezing and shortness of breath), respiratory irritation and effects similar to ingestion. Swallowing may cause nausea and diarrhea.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for ingestion and allergic reactions.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire. Combustion will generate oxides of carbon, nitrogen and sulfur.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect spilled material in a manner that minimizes the generation of airborne dust. Avoid the use of a vacuum cleaner unless explosion-proof. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Exposure guidelines:**

| | |
|--------------------|------------------|
| Cefotetan Disodium | None Established |
|--------------------|------------------|

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If airborne dust is generated, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves and clothing recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White to pale yellow powder

Odor: None

| | |
|--|---|
| Odor threshold: Not applicable | pH: Not applicable |
| Melting point/freezing point: No data available | Boiling Point: Not applicable |
| Flash point: Not applicable | Evaporation rate: Not applicable |
| Flammability (solid, gas): Not flammable | VOC: Not applicable |
| Flammable limits: LEL: Not applicable | UEL: Not applicable |
| Vapor pressure: Not applicable | Relative vapor density: Not applicable |
| Relative density: No data available | Solubility(ies): Soluble |
| Partition coefficient: n-octanol/water: No data available | Auto-ignition temperature: No data available |
| Decomposition temperature: No data available | Dynamic Viscosity: Not applicable |
| Particle Characteristics: No data available | Kinematic Viscosity: Not applicable |

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon, nitrogen and sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dusts may cause an allergic respiratory reaction with asthma symptoms (wheezing and shortness of breath), respiratory irritation and effects similar to ingestion.

Ingestion: Swallowing may cause nausea and diarrhea.

Skin contact: May cause mild irritation. Repeated skin contact may cause an allergic skin reaction.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Cefotetan disodium is a skin and respiratory sensitizer.

Germ Cell Mutagenicity: Cefotetan disodium was not mutagenic in laboratory tests.

Reproductive Toxicity: Cefotetan has adverse effects on the testes of prepubertal rats. Subcutaneous administration of 500 mg/kg/day on days 6-35 of life (thought to be developmentally analogous to late childhood and prepuberty in humans) resulted in reduced testicular weight and seminiferous tubule degeneration in 10 of 10 animals. Affected cells included spermatogonia and spermatocytes; Sertoli and Leydig cells were unaffected. Incidence and severity of lesions were dose-dependent; at 120 mg/kg/day, only 1 of 10 treated animals was affected, and the degree of degeneration was mild. Similar lesions have been observed in experiments of comparable design with other methylthiotetrazole-containing antibiotics and impaired fertility has been reported, particularly at high dose levels. No testicular effects were observed in 7-week-old rats treated with up to 1000 mg/kg/day SC for 5 weeks, or in infant dogs (3 weeks old) that received up to 300 mg/kg/day IV for 5 weeks. The relevance of these findings to humans is unknown.

Carcinogenicity: Not listed as a carcinogen or suspected carcinogen by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Cefotetan Disodium: Oral LD50>10,000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

| | UN Number | Proper shipping name | Hazard Class | Packing Group | Environmental Hazard |
|------|-----------|----------------------|--------------|---------------|----------------------|
| DOT | | Not Regulated | | | |
| TDG | | Not Regulated | | | |
| IMDG | | Not Regulated | | | |
| IATA | | Not Regulated | | | |

Transport in bulk according IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA hazard classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: N/A

Disclaimer: The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.