



MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT and Company Identification

PRODUCT: CEFOTAN® (Cefotetan for Injection, USP) 1 g and 2 g

Manufactured for:
Teligent Pharma Inc.
105 Lincoln Avenue
Buena, New Jersey 08310
Phone: 856-697-1441

Poison Control Center: 1 – 800 – 222 – 1222

This MSDS is written to provide health and safety information for individuals who will be handling the product during manufacture and packaging. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 2: Hazards Identification

Emergency overview: The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) provides the necessary drug safety information.

Potential health effects

Routes of exposure: Inhalation. Ingestion. Skin contact. Eye contact.

Eyes: Contact with eyes may cause irritation.

Skin: May cause skin irritation. May be absorbed through the skin.

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Avoid breathing vapors or mists of this product. May be irritating. Prolonged inhalation may be harmful. Allergic reactions are possible.

Ingestion: Ingestion may cause gastrointestinal irritation. Components of the product may be absorbed into the body by ingestion. Do not ingest.

Potential environmental effects may cause long-term adverse effects in the environment.

SECTION 3: Composition and Ingredients

<u>Ingredients</u>	<u>CAS No.</u>	<u>Quantity</u>	<u>LD50 (oral rat)</u>
Cefotetan Disodium	74356-00-6	1 g and 2 g vial	> 10 g/kg

Other ingredients: 80 mg Sodium per gram of Cefotetan activity.

SECTION 4: First Aid Measures

After Eye Contact: Immediately flush with water for at least 15 minutes. If irritation continues, seek medical attention.

After Skin Contact: Remove contaminated clothing immediately. Flush area with soap and water for at least 15 minutes. Seek medical attention.

After Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

After Ingestion: This product is not intended for ingestion. In case of accidental ingestion, flush out mouth with water immediately, Seek medical attention.

General advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Symptomatic treatment and supportive therapy as indicated. Cefotetan is dialyzable. Refer to the prescribing information for further details.



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SECTION 5: FIRE FIGHTING MEASURES

- Flammable properties:** Not available
- Extinguishing media:** Water spray, dry chemical, foam or Carbon dioxide (CO₂) as appropriate to surroundings.
- Fire Fighting Instructions:** Wear approved breathing apparatus and full protective turn out gear.
- Specific hazards arising from the chemical:** When heated to decomposition, toxic fumes may be emitted.
- Fire fighting equipment/ instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- Personal Safeguards:** Avoid all points of contact. Wear safety goggles or shield. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- Environmental Precautions:** Treat dispose in accordance with all regulations.
- Spill Clean-up Procedures:** Wear recommended personal protective equipment. Moisten spillage with dilute Sodium Hydroxide (0.1M). Wash the spillage area clean with liquid decontaminant (water and detergent Containing Sodium Hydroxide)

SECTION 7: Handling and Storage

- Handling procedures:** Avoid all contact and inhalation of dust, fumes, mist and/or vapors associated with the product. Follow all MSDS and label precautions.
- Storage:** The vials should not be stored at temperatures above 20°C - 25°C (68°F - 77°F); and should be protected from light.

SECTION 8: Exposure Controls and Personal Protection

Personal Protection Equipment:

- Ventilation:** Good general ventilation is sufficient to control airborne levels.
- Eye Protection:** Wear safety glasses or goggles if eye contact is possible.
- Skin Protection:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.
- Hand Protection:** Wear protective gloves to avoid repeated skin contact.
- Respiratory Protection:** With satisfactory ventilation, respirator protection is usually not required.

SECTION 9: Physical and Chemical Properties

- Description:** White to pale-yellow powder
- pH** 4.5 – 6.5 (reconstituted)
- Boiling Point:** Not available
- Freezing Point:** Not available
- Melting Point:** Not available
- Vapor Density:** Not available
- Vapor Pressure:** Not available
- Evaporation Rate:** Not available
- Solubility in Water:** Soluble
- Flash Point:** Not available



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SECTION 10: STABILITY AND REACTIVITY

- Stable:** Material is stable under normal conditions.
- Conditions to Avoid:** Direct sunlight, conditions that might generate heat, and sources of ignition.
- Hazardous Decomposition:** If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and sulfur oxides).

SECTION 11: TOXIOLOGICAL INFORMATION

- Signs and Symptoms of Exposure and Overexposure:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reaction from prescribed doses and overdoses are described in the package insert. Occupational exposure has not been fully investigated.
- Skin Sensitivity:** No data available
- Eye Sensitivity:** No data available
- Respiratory Sensitization:** No data available
- Carcinogenicity:** **IARC:** No component of this product present at levels greater than or equal to 0.1% as a carcinogen or a potential carcinogen by IARC.
- Reproductive Toxicity:** No data available
- Specific Target Organ Toxicity:** No data available

SECTION 12: ECOLOGICAL INFORMATION

The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

- Product Disposal:** Dispose of in accordance with all applicable federal, state and local regulations. Dispose in accordance with all applicable regulations.

SECTION 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT (transportation by land), IATA (transportation by sea) or IMDG (transportation by air) regulations.

SECTION 15: REGULATORY INFORMATION

The product described in this MSDS are regulated under the Federal Food, Drug and Cosmetics Act and are safe to use as per directions on container, box or accompanying literature (where applicable). The finished product is labeled in compliance with the requirements of the FDA and must be used in prescribed manner.

SECTION 16: OTHER INFORMATION

The information contained in this Material Safety Data Sheet has been compiled from information believed to be accurate and from past experience. While we believe that the data presented is factual, Teligent Pharma, Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.