

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078950147

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078950148

### SECTION 01 – IDENTIFICATION

**Belcher Pharmaceuticals, LLC.**  
12393 Belcher Road, Suite # 420B  
Largo, FL 33773

**Telephone:** 1-727-471-0850  
**Emergency Phone:** 1-727-471-0850

**Product Name:** Cephalexin Capsules USP, 250 mg or 500 mg.

**Synonyms:** Not Applicable.

**Therapeutic Use:** Cephalexin Capsules USP, 250 mg and 500 mg is an antibiotic; a cephalosporin intended for the treatment of bacterial infections. It is indicated for the treatment of Respiratory tract infections caused by *Streptococcus pneumoniae* and Otitis media due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Moraxella catarrhalis*. Also used for the treatment of skin and skin structure infections caused by *Staphylococcus aureus* and *Staphylococcus pyogens*; bone infections caused by *Staphylococcus aureus* and *Proteus mirabilis*; Genitourinary tract infections, including acute prostates, caused by *Escherichia coli*, *Proteus mirabilis*, and *Klebsiella pneumoniae*.

**Restrictions on Use:** Cephalexin Capsules are contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

**Description:** **For Cephalexin 250 mg:**  
Size 2 con-snap, empty hard gelatin capsules, white opaque cap and white opaque body, Imprinted with "801" on the cap with black ink filled with white to off white powder.

**For Cephalexin 500 mg:**  
Size 0 con-snap, empty hard gelatin capsules, white opaque cap and white opaque body, Imprinted with "802" on the cap with black ink filled with white to off white powder.

### SECTION 02 – HAZARD(S) IDENTIFICATION

**Hazard Statement:** May cause allergic reaction.

**Signal Word:** Warning.

**Eye:** Irritation might occur following direct contact with eyes.

**Skin:** Irritation might occur following direct contact.

**Inhalation:** Can produce respiratory irritation. Adverse effects might occur following inhalation.

**Ingestion:** Not expected to be toxic following ingestion.



### SECTION 03 – COMPOSITION AND INFORMATION ON INGREDIENTS

Ingredients	CAS Number	Amount
Cephalexin, USP	23325-78-2	250 mg or 500 mg
Inactive Ingredients	CAS Number	Amount
Anhydrous Lactose, NF	63-42-3	Trade Secret
Talc, USP	14807-96-6	Trade Secret
Magnesium Stearate, NF	557-04-0	Trade Secret

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**SECTION 04 – FIRST AID MEASURES**

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- Eyes:** Immediately flush eyes with plenty of water. Get medical attention.
- Skin:** Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
- Inhalation:** Move the individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
- Ingestion:** If swallowed, get medical attention immediately. Do not induce vomiting. Never attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious.

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**SECTION 05 – FIRE FIGHTING MEASURES**

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- General Hazard:** Not known.
- Fire Fighting Instructions:** For single units (packages): No special requirements needed.  
For larger amounts (multiple packages/ pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
- Extinguisher to Use:** Use water spray, carbon dioxide, dry chemical powder or appropriate foam.
- Flash Point:** Not known.
- Auto-ignition:** Not known.
- Flammability Limits:** Not known.
- Hazardous Combustion Products:** Hazardous combustion or decomposition products are expected when the product is exposed to fire.
- Minimum Explosive Concentration for Dust / Vapor:** Not known.

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**SECTION 06 – ACCIDENTAL RELEASE MEASURES**

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- Protective Equipment:** Personnel involved in clean-up should wear appropriate equipment (see section 8). Minimize exposure.
- Occupational Spill:** Contain the source of spill or leak. Scoop spilled material into a labeled container for recovery or disposal. Clean spill area thoroughly with detergent and water.
- Clean-up – Large Spill:** Review Sections 02 and 08 proceeding with the clean up. Contain the source of the spill or leak. Eliminate possible ignition sources and follow appropriate grounding procedures. Scoop or shovel spilled material into a labeled container for recovery or disposal. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. Large spills may be subject to EPA/CERCLA Section 103 Release Report Requirements.

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**SECTION 07 – HANDLING AND STORAGE**

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**General Handling:** Keep away from heat. Avoid creating dust when handling. Use with adequate ventilation.

**Storage:** Protect from moisture of direct sunlight.

**Incompatible Materials:** None Known.

**Temperature Range:** Store at 20°C to 25°C (68° to 77°F) Excursions permitted to 15°C to 30°C; [See USP Controlled Room Temperature].

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**SECTION 08 – EXPOSURE CONTROLS / PERSONAL PROTECTION**

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**OSHA's Permissible Exposure Limits (PELs):** None established.

**ACGIH Threshold Limit Values (TLVs):** Data not available.

**Engineering Controls:** No specific measures necessary. Good general room ventilation is expected to be adequate.

**Personal Protective Equipment:** Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. Refer to below recommended protection.

**Eye Protection:** Chemical goggles and/ or face shield.

**Skin Protection:** Body covering to minimize skin contact.

**Hand Protection:** Chemical – resistant gloves.

**Respiratory Protection:** None required under normal and foreseeable conditions of use. Use dust mask for dusty condition.

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**SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES**

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**Physical Form:** Capsules.

**Color:** White.

**Odor:** Odorless.

**Molecular Weight:** Not applicable.

**Molecular Formula:** Not applicable.

**pH:** Not applicable.

**Melting Point:** Not applicable.

**Vapor Pressure:** Not applicable.

**Water Solubility:** Slightly soluble.

**Solvent Solubility:** Not applicable.

### SECTION 10 – STABILITY AND REACTIVITY

**Chemical Stability:** Stable under recommended storage conditions.

**Reactivity:** None Known.

**Conditions to Avoid:** None known.

**Incompatibilities:** None Known.

**Hazardous Polymerization:** Will not occur.

**Hazardous Decomposition Products:** May emit toxic fumes when heated to decomposition.

**Oxidizing Properties:** May reacts with strong oxidizing agents.

**Explosive Properties:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

### SECTION 11 – TOXICOLOGICAL INFORMATION

**Oral Toxicity:** Not expected to be toxic following ingestion.

**Inhalation Toxicity:** Can produce respiratory irritation. Adverse effects might occur following inhalation.

**Skin Effects:** Irritation might occur following direct contact.

**Eye effects:** Irritation might occur following direct contact with eyes.

**Gastrointestinal Reactions:** Symptoms of Pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia, gastritis, and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

**Hypersensitivity Reactions:** Allergic reactions in the form of rash, urticaria, angioedema, and rarely, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. In some of these reactions, supportive therapy may be necessary. Anaphylaxis has also been reported.

**Genetic Toxicity:** Not expected to be genotoxic based on animal studies.

**Carcinogenicity:** Not expected to be carcinogenic based on animal studies.

### SECTION 12 – ECOLOGICAL INFORMATION

**Environmental Overview:** No relevant studies identified.

### SECTION 13 – DISPOSAL CONSIDERATIONS

**Disposal Procedure:** Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State, Local environmental regulations and Site conditions may affect proper disposal.

### SECTION 14 – TRANSPORT INFORMATION

**Proper Shipping Name:** Cephalexin Capsules USP, 250 mg or 500 mg.

**General Shipping Instructions:** Non-regulated.

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**SECTION 15 – REGULATORY INFORMATION**

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No Data Available.

**Labeling on Container to Include:** Product Name, Batch Number, Expiry Date, Storage Conditions, Company Name and Address.

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**SECTION 16 – OTHER INFORMATION**

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