安成國際藥業股份有限公司
TWi Pharmaceuticals, Inc.

Safety Data Sheet

Cephalexin For Oral Suspension USP, 125mg/5ml or 250mg/5ml

SECTION 1 IDENTIFICATION

Product identifier	Cephalexin For Oral Suspension USP, 125mg/5ml or 250mg/5ml
Recommended use	Powder for oral suspension
Supplier	
Company name	TWi Pharmaceuticals USA, Inc.
Address	115 West Century Road, Suite 180, Paramus, NJ 07652
Telephone	1- 201-762-1405
Fax	1- 201-225-0051
E-mail address	QA.Service@twipharma.com
Emergency phone number	1-844-518-2989

SECTION 2 HAZARD IDENTIFICATION

Appearance	White to off-white powder.
Physical State	Solid
Routes of Entry	Inhalation and skin contact.
Effects of Overexposure	Eye irritation and allergic reactions to Cephalexin have been reported. Based on prior experience with cephalosporin antibiotics, allergic reactions may include rash, nasal congestion, cough, dry throat, gastrointestinal upset, eye irritation, or anaphylactic shock.
Medical Conditions Aggravated by Exposure	Hypersensitivity to penicillin or cephalosporin
Carcinogenicity	Cephalexin -No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA. Contains no hazardous component (one percent or greater) or carcinogens (one-tenth or percent or greater) not listed above

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS#	Concentration %
Cephalexin	15686-71-2	5% or 10%
Non-hazardous excipients	N/A	95% or 90%

SECTION 4 FIRST-AID MEASURES

Instructions by routes of exposure

Skin contact	If dust from broken or crushed capsules comes in contact with skin and clothing, remove contaminated clothing and wash exposed areas of skin thoroughly with running water for at least 15 minutes. Use soap if available. Seek medical attention if irritation develops.

Eye contact	Hold eyelids open and flush with a steady, gentle stream of water for 15minutes.See an ophthalmologist (eye doctor) or other physician immediately.
Ingestion	Do not induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Call a physician or poison control center. In case of acute overdose by ingestion, seek immediate medical attention.

SECTION 5 FIRE-FIGHTING MEASURES

Flash point	Not flammable.
Fire Fighting Extinguishing Media	In case of fire use water, carbon dioxide, foam or dry chemical.
Unusual Fire and Explosion Hazards	As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Wear protective clothing and equipment with the degree of hazard.
Methods and materials for containment and cleanup	Collect and place it in a suitable, properly labeled container for recovery or disposal.
Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

SECTION 7 HANDLING AND STORAGE

Conditions for safe storage, including any incompatibilities	Store at 20℃ - 25℃ (68℃ to 77℉) [See USP Controlled Room Temperature].

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Under normal use and handling conditions, no protective equipment is required.

The following is recommended for a production setting:
Wear appropriate clothing to avoid skin contact. Wash hands and arm thoroughly after handling.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

The following properties apply to the active ingredient, Cephalexin:

Appearance	
Physical state/ Form/ Color	White to off-white crystalline powder.
Chemical Formula	C16H17N3O4S
Molecular Weight	347.39
Melting point	196-198°C
Initial boiling point and boiling	N/A

range	
Specific Gravity	N/A
Solubility	NH4OH 1 M: 50 mg/ml, clear, yellow

SECTION 10 STABILITY AND REACTIVITY

Stable under recommended storage conditions.

SECTION 11 TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure (short-term exposure)

Inhalation	Can produce respiratory irritation. Adverse effects might occur following inhalation.
Skin contact	Irritation might occur following direct contact.
Eye contact	Irritation might occur following direct contact.
Ingestion	Not expected to be toxic following ingestion

Toxicology (long-term exposure)

Genetic toxicity	Not expected to be genotoxic based on animal studies.
Carcinogenicity	Not expected to be Carcinogenicity based on animal studies.

SECTION 12 ECOLOGICAL INFORMATION

Very toxic to aquatic organisms with long-lasting effects

Ecotoxicity	Hydroquinone is classified in the EU as very toxic to aquatic organisms, with an M factor of 10 for chronic toxicity. EC50 daphnia magna 0.134 mg/L/48 hr. NOEC daphnia magna 0.0057 mg/L/21 d. (OECD 211)
Persistence and degradability	Hydroquinone is readily biodegradable
Bioaccumulative potential	No data is available
Mobility in soil	No data is available
Other adverse effects	None known

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal instructions	Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended

SECTION 14 TRANSPORT INFORMATION

Not a regulated material for transport.

SECTION 15 REGULATORY INFORMATION

No information found.

SECTION 16 OTHER INFORMATION

No information found.

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