

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** Ceftriaxone for Injection, USP  
**Manufacturer Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
 Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** January 08, 2009  
**SDS Revision Date:** June 10, 2015  
**(M)SDS Format:**

### SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



**Signal Word:** DANGER.

**GHS Class:** Serious Eye Damage. Category 1.  
 Skin corrosion. Category 1.  
 Respiratory sensitisation. Category 1.  
 Skin Sensitization. Category 1.

**Hazard Statements:** Causes serious eye damage.  
 Causes severe skin burns and eye damage.  
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 May cause an allergic skin reaction.

**Precautionary Statements:** Do not breathe dust/fume/gas/mist/vapours/spray.  
 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 Wash hands thoroughly after handling.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 In case of inadequate ventilation wear respiratory protection.  
 IF SWALLOWED: Rinse mouth. Do not induce vomiting.  
 IF ON SKIN: Wash with plenty of water.  
 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 Immediately call a POISON CENTER or doctor/physician.  
 Specific treatment (see ... on this label).  
 If skin irritation or rash occurs: Get medical advice/attention.  
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
 Take off contaminated clothing and wash it before reuse.  
 Wash contaminated clothing before reuse.  
 Store locked up.  
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

**Route of Exposure:** Inhalation Ingestion Eye contact Skin Absorption. Injection.

**Potential Health Effects:**

**Eye:** Contact with eyes may cause irritation.

**Signs/Symptoms:** Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: hypersensitivity (rash, pruritus, fever, chills), hematologic (eosinophilia, thrombocytosis, leukopenia), gastrointestinal (diarrhea), elevated liver function tests, elevated BUN, central nervous system (headache, dizziness), genitourinary (moniliasis, vaginitis), diaphoresis, and flushing. Occupational exposure has not been fully investigated.

**Aggravation of Pre-Existing Conditions:** Previous allergic reaction to penicillins, penicillin derivatives, penicillamine, or cephalosporins. History of bleeding disorders, gastrointestinal disease, hepatic and renal function impairment.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Ceftriaxone Sodium	104376-79-6	250 mg, 500 mg, 1 gm, 2 gm, and 10 gm	

## SECTION 4 : FIRST AID MEASURES

<b>Eye Contact:</b>	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
<b>Skin Contact:</b>	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
<b>Ingestion:</b>	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
<b>Other First Aid:</b>	For Adverse Event Information, please call (800) 551-7176.

## SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
<b>Extinguishing Media:</b>	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

<b>Personnel Precautions:</b>	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	This material will settle out of the air.
<b>Methods for cleanup:</b>	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

## SECTION 7 : HANDLING and STORAGE

<b>Handling:</b>	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
<b>Storage:</b>	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light.
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A

NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/npptl/topics/respirators/>) for a list of respirator types and approved suppliers.

**Other Protective:**

Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

**SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES**

Physical State:	Crystalline powder.
Color:	White to pale yellow.
Odor:	No information.
Odor Threshold:	No information.
Boiling Point:	Not established.
Melting Point:	> 155°C Decomposes.
Density:	No information.
Specific Gravity:	No information.
Specific Volume:	No information.
Solubility:	470,000 mg/l in water. (22 °C) 32,000 mg/l IN METHANOL (22 °C) 200 mg/l IN ACETONE (22 °C)
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
Evaporation Rate:	No information.
pH:	6.7 in 1% Aqueous solution
Molecular Formula:	Mixture
Molecular Weight:	661.59
Viscosity:	No information.
Coefficient of Water/Oil Distribution:	No information.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	No information.

**SECTION 10 : STABILITY and REACTIVITY**

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

**SECTION 11 : TOXICOLOGICAL INFORMATION**

**Ceftriaxone Sodium :**

OSHA:	Not listed
IARC:	Not listed
NTP:	Not listed

**Ceftriaxone Sodium :**

Ingestion:	LD50 Oral Rat: > 10,000 mg/kg LD50 Oral Mouse: > 10,000 mg/kg (RTEC)
Sensitization:	Hypersensitivity reactions may be occurred by injections.
Mutagenicity:	Ceftriaxone showed no potential for mutagenic activity.
Reproductive Toxicity:	Ceftriaxone produced no impairment of fertility when given intravenously to rats.
Other Toxicological Information:	LD50 Intravenous rat 1900 mg/kg (RTEC)

**SECTION 12 : ECOLOGICAL INFORMATION**

**Ecotoxicity:** No ecotoxicity data was found for the product.  
**Environmental Stability:** No environmental information found for this product.

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### SECTION 13 : DISPOSAL CONSIDERATIONS

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**Waste Disposal:** Dispose of in accordance with Local, State, Federal and Provincial regulations.

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### SECTION 14 : TRANSPORT INFORMATION

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**DOT Shipping Name:** Not Regulated.  
**DOT UN Number:** Not Regulated.

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### SECTION 15 : REGULATORY INFORMATION

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### SECTION 16 : ADDITIONAL INFORMATION

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**HMS Ratings:**

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