SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Cefazolin 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 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Eye Irritation. Category 2.
Skin Irritation. Category 2.
Skin Sensitization. Category 1.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Causes serious eye irritation.
Causes skin irritation.
May cause an allergic skin reaction.

Precautionary Statements:
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 ON SKIN: Wash with plenty of water.
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.
Specific treatment (see ... on this label).
If skin irritation occurs: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
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. Side effects from therapeutic doses include: gastrointestinal, allergic, hematologic, renal, and hepatic laboratory abnormalities. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with known allergy to the cephalosporin and penicillin group of antibiotics.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Cefazolin Sodium	27164-46-1	500 mg, 1 gm, 10 gm, and 20 gm vials	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	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.
Skin Contact:	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.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	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.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	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.
Extinguishing Media:	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.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	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

Personnel Precautions:	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.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Handling:	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.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	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.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	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 yellow
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	198 - 200 °C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.6 - 6.0
Molecular Formula:	Mixture
Molecular Weight:	476.52
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Avoid direct sunlight, conditions that might generate heat, and sources of ignition. Avoid dispersion as dust cloud.

SECTION 11 : TOXICOLOGICAL INFORMATION

Cefazolin Sodium :

Acute Toxicity:

IMMEDIATE EFFECTS: Eye, skin and respiratory irritation may occur. Classified as a non-irritant to rabbit skin. No signs of irritation occurred after 3 minute, 1 hour or up to 3 days after direct application in rabbits for four hours. Classified as a mild irritant in rabbit eyes. Signs of irritation, such as redness or swelling occurred after direct application in rabbits. Eyes appeared normal after 7 days.

Acute Toxicity:
LD50 IV Rat: 2760 mg/kg

Cefazolin Sodium :

RTECS Number: XI0390000

Acute Effects: Eye, skin and respiratory irritation may occur. Classified as a non-irritant to rabbit skin. No signs of irritation occurred after 3 minute, 1 hour or up to 3 days after direct application in rabbits for four hours. Classified as a mild irritant in rabbit eyes. Signs of irritation, such as redness or swelling occurred after direct application in rabbits. Eyes appeared normal after 7 da

Ingestion: Oral - Rat LD50: >11 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: >11 gm/kg [Details of toxic effects not reported other than lethal dose value]

Chronic Effects: DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.

Other Toxicological Information: Intravenous. - Rat LD50: 2760 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Mouse LD50: 3900 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit LD50: 2500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rat TDLo: 21 gm/kg/21D (intermittent) [Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - other changes in urine composition Nutritional and Gross Metabolic - changes in chlorine]
Intravenous. - Rat TDLo: 42875 mg/kg/5W (intermittent) [Gastrointestinal - other changes Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intravenous. - Rabbit TDLo: 2800 mg/kg/7D (intermittent) [Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases Related to Chronic Data - death]
Intravenous. - Rabbit TDLo: 4200 mg/kg/21D (intermittent) [Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - other changes in urine composition Kidney/Ureter/Bladder - other changes]
Intravenous. - Rat TDLo: 5500 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Fertility - litter size (e.g. number fetuses per litter; measured before birth) Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)]
Intravenous. - Rat TDLo: 5500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]
Intravenous. - Rat TDLo: 21 gm/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes Reproductive - Maternal Effects - uterus, cervix, vagina Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]
Intravenous. - Rat TDLo: 21 gm/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]

Subcutaneous - Rat LD50: 10 gm/kg [Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold Gastrointestinal - hypermotility, diarrhea]
Subcutaneous - Mouse LD50: 7600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit LD50: >6 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat TDLo: 112 gm/kg/28D (intermittent) [Blood - normocytic anemia Blood - changes in bone marrow (not otherwise specified) Related to Chronic Data - changes in prostate weight]
Subcutaneous - Rat TDLo: 91 gm/kg/13W (intermittent) [Endocrine - changes in spleen weight Blood - changes in spleen Skin and Appendages - dermatitis, other (after systemic exposure)]
Intraperitoneal. - Rat LD50: 7400 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 6200 mg/kg [Details of toxic effects not reported other than lethal dose value]

Chronic Effects: DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

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

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated..

SECTION 15 : REGULATORY INFORMATION

EINECS Number: 248-278-4

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date: January 08, 2009

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