SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Imipenem and Cilastatin 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:	December 09, 2011
SDS Revision Date:	February 03, 2025

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: WARNING.

GHS Class:
Eye Irritation. Category 2.
Skin Irritation. Category 2.

Hazard Statements:
Causes serious eye irritation.
Causes skin irritation.

Precautionary Statements:
Wash hands thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water.
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 eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.

Emergency Overview:
Irritant. May cause sensitization by inhalation and skin contact. Harmful if swallowed.
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: May cause irritation.
- Skin: May cause an allergic skin reaction. May be harmful if absorbed through skin.
- Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Ingestion: Harmful if swallowed. Ingestion can cause nausea, vomiting, diarrhea and gastrointestinal irritation.

Chronic Health Effects:
Chronic exposure to inhaled sodium carbonate may cause perforation of the nasal septum. Prolonged contact with skin causes dermatitis and ulceration.

Signs/Symptoms:
Gastrointestinal (nausea, diarrhea, vomiting, tongue papillar hypertrophy, pseudomembranous colitis, hemorrhagic colitis, gastroenteritis, abdominal pain, glossitis, heartburn, pharyngeal pain, increased salivation); CNS (fever, dizziness, seizures somnolence, confusion, myoclonus, vertigo, headache, encephalopathy, paresthesia); special senses (transient hearing loss in patients with impaired hearing, tinnitus); respiratory (dyspnea, hyperventilation, thoracic spine pain); cardiovascular (hypotension, palpitations, tachycardia); Renal (oliguria/anuria, polyuria); skin (rash, pruritus, urticaria, skin texture changes, candidiasis, erythema multiforme, facial edema, flushing, cyanosis, hyperhidrosis, pruritus vulvae; Body as a whole (polyarthralgia, asthenia/weakness).
Adverse laboratory changes, without regard to drug relationship, that were reported during clinical trials were: hepatic (increased SGPT, SGOT, alkaline phosphatase, bilirubin and LDH); hemic (increased eosinophils, positive Coombs' test, decreased WBC and neutrophils, increased WBC, increased platelets, decreased platelets, decreased, hemoglobin and hematocrit, increased monocytes, abnormal prothrombin time, increased lymphocytes, increased basophils); electrolytes (decreased serum sodium, increased potassium, increased chloride); renal (increased BUN, creatinine); Urinalysis (presence of urine protein, urine red blood cells, urine white blood cells, urine casts, urine bilirubin, and urine urobilinogen).

Aggravation of Pre-Existing Conditions:
Individuals with hypersensitivity to any component of this product.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Cilastatin Sodium	81129-83-1	49 %
Imipenem Monohydrate	74431-23-5	49 %
Sodium Bicarbonate	144-55-8	2 %

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:	Imipenem monohydrate: 296 °C.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Imipenem monohydrate Ignition temperature in layer: from 17.21 ° C, the sample does not ignite until the maximum temperature of 400 °C. Auto ignition temperature in cloud: at room pressure the sample is non-flammable up to 450 °C. Cilastatin sodium Auto flammability in cloud is non-flammable at room pressure up to 430 °C. Ignition temperature in layer: at the temperature of 17.21 °C and density of charge equal to 0.51 g/cm3, the sample does not ignite until the maximum temperature of 400 ° C.
Lower Flammable/Explosive Limit:	Imipenem monohydrate: 40 g/m3 Cilastatin sodium: 150 g/m3
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:	Imipenem monohydrate: after 7.5 minutes it shows the presence of ammonia, methane, carbon dioxide, carbon monoxide and carbonyl sulfide. Cilastatin sodium: after 39.5 minutes, at an interval of heating ranging from 30 to 900 °C, it is detected the presence of carbon dioxide (CO2), ammonia, carbon monoxide (CO), carbonyl sulfide, methane, and the long chain type 3 nonanone. Sodium carbonate: the substance during the incomplete combustion can emit carbon monoxide, carbon dioxide and sodium compounds.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal 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:	Clean up promptly by sweeping or vacuum. Avoid dust formation. Pick or scoop up material and put into a suitable container for proper disposal.

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. Use antistatic bags and grounding procedures equipment. Avoid static discharges accumulation.
Storage:	Should be stored at room temperature, approximately 25°C (77°F).
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 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:	Solid.
Color:	White
Odor:	Odorless.
Boiling Point:	Imipenem Monohydrate: 567,3° C at 760 mmHg Cilastatin Sodium: 655 °C at 760 mmHg
Melting Point:	Sodium carbonate: 851 °C.
Solubility:	IMIPENEM MONOHYDRATE: WATER SOLUBILITY: 10 mg/ml. OTHER SOLUBILITIES: SLIGHTLY SOLUBLE IN METHANOL, PRACTICALLY INSOLUBLE IN ETHANOL, IN DIMETHYLFORMAMIDE, AND IN DIMETHYL SULFOXIDE (DMSO). CILASTATIN SODIUM: SOLUBLE IN WATER AT 100 MM, AND IN DMSO AT 10 MM. SOLUBLE IN METHANOL. SODIUM CARBONATE: IDROSOLUBILITY: 170 g/l. OTHER SOLUBILITIES: SOLUBLE IN GLYCEROL, SLIGHTLY SOLUBLE IN ETHANOL. SOLUBLE IN TRICHLOROMETHANE.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	6.5 - 8.5
Molecular Formula:	Mixture
Flash Point:	Imipenem monohydrate: 296 °C.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Imipenem monohydrate Ignition temperature in layer: from 17.21 ° C, the sample does not ignite until the maximum temperature of 400 °C. Auto ignition temperature in cloud: at room pressure the sample is non-flammable up to 450 °C. Cilastatin sodium Auto flammability in cloud is non-flammable at room pressure up to 430 °C. Ignition temperature in layer: at the temperature of 17.21 °C and density of charge equal to 0.51 g/cm3, the sample does not ignite until the maximum temperature of 400 ° C.
Explosive Properties:	Imipenem monohydrate explosion parameters: maximum pressure (Pmax) = 9,4 bar; maximum increase of rate pressure (dP/dt)max = 614 bar/s; maximum value of Kst= 167 bar. m/s (St1class)

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from moisture. Avoid static discharges. Keep away from open flames, direct lighting, heat and auto-ignition sources.

SECTION 11 : TOXICOLOGICAL INFORMATION

Cilastatin Sodium :

RTECS Number:	MJ9650200
Ingestion:	Oral - Rat LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Mutagenicity:	No mutagenic activity detected

Teratogenicity:	No teratogenic effect
Other Toxicological Information:	Intravenous. - Rat LD50 : 5027 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50 : >10 gm/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Pleural thickening]

Imipenem Monohydrate :

RTECS Number:	CL5446516
Mutagenicity:	No mutagenic activity detected
Teratogenicity:	No teratogenic effect
Other Toxicological Information:	Intracerebral - mouse TDLo: 174 ug/kg [Behavioral - convulsions or effect on seizure threshold]

SECTION 12 : ECOLOGICAL INFORMATION

Cilastatin Sodium :

Bioaccumulation:	Log Pow: -1,177.
Effect of Material On Aquatic Life:	Daphnia Magna EC50: 29,700 mg/l/48hours.

Imipenem Monohydrate :

Biodegradation:	Imipenem monohydrate degrades rapidly
Bioaccumulation:	LogP: -0.770. Calc. LogP (KowWin): -1.17.
Effect of Material On Aquatic Life:	Daphnia magna LC50: 100 mg/l/48 hours.

Sodium Bicarbonate :

Ecotoxicity:	Very polluting the air and extremely toxic to plants
Biodegradation:	Sodium carbonate hydrolyzes in water and decomposes in acidic media
Bioaccumulation:	LogP: 0.
Effect of Material On Aquatic Life:	Fish LC50: 750 mg/l/96 hours. Crustaceans, EC50: 565 mg/l/48 hours. Long-term effects: Fish, LC100: 68-70 mg/l/5 days.

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

Imipenem Monohydrate :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2
HMIS Fire Hazard:	1
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	December 09, 2011
SDS Revision Date:	February 03, 2025
SDS Revision Notes:	Overall SDS review - no changes to formulation.
Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.