

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Pentam 300
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
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(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.
 Reproductive toxicity, Category 2.
 Skin Sensitization, Category 1.
 Reproductive toxicity, Effects on or via lactation.

Hazard Statements: Causes serious eye damage.
 Causes severe skin burns and eye damage.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Suspected of damaging fertility or the unborn child.
 May cause an allergic skin reaction.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 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.
IF exposed or concerned: Get medical advice/attention.
 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: Signs and symptoms of overdosage are not known. Occupational exposure has not been fully investigated.
 Side effects from therapeutic doses include hypotension, hypoglycemia, acute pancreatitis, cardiac arrhythmias, and nephrotoxic events. Signs and symptoms of overdosage are not known. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Pre-existing hypertension, hypotension, ventricular tachycardia, hypoglycemia, hyperglycemia, hypocalcemia, pancreatitis, leukopenia, thrombocytopenia, anemia, hepatic or renal dysfunction, and Stevens-Johnson syndrome.

Pentamidine Isethionate

Skin: Rash has been reported.

Inhalation: Respiratory Irritation: Bronchospasm, shortness of breath, severe pulmonary irritation, delayed or immediate pulmonary edema, irritation of mucous membranes of the nose, eyes, and respiratory tract have been reported to occur in inhalation exposure. Respiratory irritation may continue to worsen from 24 to 72 hours after exposure, seek medical attention if any signs of respiratory irritation continue to persist.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Pentamidine Isethionate	140-64-7	300 mg/vial	

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 15 to 30°C (59 to 86°F). 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/nppt/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:	Lyophilized powder.
Color:	White
Boiling Point:	Not established.
Melting Point:	180°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.5 - 7.5 (reconstituted.)
Molecular Formula:	Mixture
Molecular Weight:	592.68
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:	Exposure to light or heat may cause decomposition.

SECTION 11 : TOXICOLOGICAL INFORMATION

Pentamidine Isethionate :

Acute Toxicity:	LD50: IV Mouse 15 mg/kg LD50: IP Mouse 63 mg/kg LD50: SC Mouse 120 mg/kg
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Pentamidine Isethionate :

RTECS Number:	CV6500000
Acute Effects:	If the following symptoms such as irritation, tearing, swelling, and photophobia persist after flushing, seek medical attention.
Skin:	IMMEDIATE EFFECTS: Rash has been reported.
Chronic Effects:	DELAYED EFFECTS: Respiratory irritation can worsen. Pentamidine isethionate is not known to be a vesicant, but necrosis has been reported with intramuscular injections and intravenous extravasation.
Other Toxicological Information:	Intravenous. - Mouse LD50: 15100 ug/kg [Behavioral - convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration - other changes] Intravenous. - Rat TDLo: 756 mg/kg/6W (intermittent) [Gastrointestinal - changes in structure or function of endocrine pancreas; Liver - changes in liver weight; Related to Chronic Data - death] Intravenous. - Rat TDLo: 24 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)] Subcutaneous - Mouse LD50: 120 mg/kg [Behavioral - convulsions or effect on seizure threshold;

Lungs, Thorax, or Respiration - other changes]
Subcutaneous - Mouse TDLo: 500 mg/kg/4W (intermittent) [Blood - normocytic anemia; Blood - changes in erythrocyte (RBC) count; Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Subcutaneous - Mouse TDLo: 500 mg/kg/4W (intermittent) [Blood - macrocytosis; Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol); Blood - changes in other cell count (unspecified)]
Subcutaneous - Mouse TDLo: 500 mg/kg/4W (intermittent) [Blood - changes in cell count (unspecified); Blood - other changes]
Intraperitoneal. - Mouse LD50: 63 mg/kg [Behavioral - convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration - other changes]

Chronic Effects:

DELAYED EFFECTS: Respiratory irritation can worsen. Pentamidine isethionate is not known to be a vesicant, but necrosis has been reported with intramuscular injections and intravenous extravasation.

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

Pentamidine Isethionate :

EINECS Number: 205-424-1
Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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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.

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