

SAFETY DATA SHEET

Pentamidine Inhalation

1. IDENTIFICATION

Product identifier: Pentamidine Inhalation

Product Codes: 0121-1102-55

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug

Restrictions on use: Use only as directed

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Eye Irritant Category 2A Skin Irritant Category 2 Skin Sensitization Category 1 Specific Target Organ Toxicity Single Exposure Category 3

Warning!

Hazard statement(s)

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

Precautionary statement(s)

Wash hands thoroughly after handling. Avoid breathing dusts or mists. Use only outdoors or in a well-ventilated area. Contaminated clothing must not be allowed out of the workplace. Wear protective gloves and eye protection.



Precautionary statement(s)

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

IF on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.

If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if you feel unwell.

Store locked up

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Pentamidine Isethionate	140-64-7	300 mg/vial

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4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or other symptoms occur, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation or rash develop, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water for several minutes while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: Causes eye and skin irritation. May cause an allergic skin reaction. May cause respiratory irritation if inhaled.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and carefully collect in a manner that minimizes the generation of airborne dust (i.e. wipe up with wet cloth or vacuum). Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust or mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

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Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Pentamidine Isethionate	None Established
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Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive or irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid	pH: 4.5-7.5
Odor: Odorless	Color: Colorless
Melting point/freezing point: 180°C	Boiling Point: Not applicable
Flash point: Not applicable	Particle Characteristics: No data available
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not applicable	Relative vapor density: Not applicable
Relative density: ~1.0	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

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Hazardous decomposition products: Thermal decomposition may yield carbon, nitrogen and sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust or mists may cause irritation of the mucous membranes and upper respiratory tract. Side effects from therapeutic doses include night sweats, diarrhea, nausea, anemia, bronchitis, pharyngitis, sinusitis, headache, chest pain, cough, wheezing, and bad taste.

Ingestion: Pentamidine is not well absorbed through the intestinal tract. Adverse effects are not expected.

Skin contact: May cause irritation. May cause an allergic skin reaction.

Eye contact: Causes irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Pentamidine is a skin sensitizer.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens.

Reproductive Toxicity: Components are not classified as reproductive toxins.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values:

Pentamidine Isethionate: Subcutaneous LD50 mouse 120 mg/kg, Intraperitoneal LD50 mouse 63 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

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Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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