



300 Northfield Road
 Bedford, OH 44146
 Telephone: (440) 232-3320
 -or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Pamidronate Disodium for Injection (30 mg per vial)
Chemical Names: Phosphoric acid,(3-amino-1-hydroxypropylidene)bis-,disodium salt
Synonyms: Aredia™, Pamidronate Disodium, CGP 23339A, Disodium Pamidronate, Disodium 3-amino-1-hydroxypropylidene-1,1-biphosphate
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: 1(800) 424-9300
Telephone Number for Info.: (440) 232-3320 or (800) 562-4797
Medical Emergency: Professional Services 1(800) 521-5169
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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Pamidronate Disodium	6%	57248-88-1	NONE	NONE	NONE
Mannitol	94%	69-65-8	NONE	10mg/m ³ (total) 3 mg/m ³ (respirable)	NONE

Pamidronate Disodium for Injection is a freeze-dried powder to be reconstituted for administration with Water for Injection

Section III - HEALTH HAZARD DATA

Routes of Entry: Exposure may occur via inhalation, ingestion, injection or skin contact.
Health Hazard (Acute & Chronic): Product is a bone-resorption inhibitor and may affect the digestive and blood systems. Chronic exposure may affect the kidneys and bone.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO
Signs & Symptoms of Exposure: May cause irritation to eyes and skin. Excessive exposure may cause pain, fatigue, transient fever, gastrointestinal disturbances and fluctuations in serum calcium and mineral levels.
Medical Conditions Generally Aggravated by Exposure: Persons who are allergic to Pamidronate Disodium or other bisphosphates.
BVL Hazard Category: 2

Section IV - FIRST AID MEASURES

Eye Exposure: Flush with large volumes of water for 15 minutes. Seek the attention of a physician.

Skin Exposure: Wash with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water; seek the attention of a physician immediately.

Inhalation: If difficulty breathing, administer oxygen. Seek the attention of a physician and provide artificial respiration if necessary.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable

Flammable Limits: None **LEL:** None **UEL:** None

Extinguishing Media: Use water or a multi-purpose extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear a self-contained breathing apparatus to avoid smoke inhalation.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet and absorb Pamidronate with towels or sorbents and dispose of according to federal, state or local regulations. Prevent spills from entering waterways.

Release to Air: If dust is generated, reduce exposures by ventilating area. Clean spills immediately to prevent evaporation.

Release to Water: Refer to local water authority. Drain disposal is not recommended.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. If aerosols are generated, a dust/mist respirator (N95) should be worn.

Waste Disposal Method: Incineration at an approved/permitted facility according to federal, state and local guidelines.

Precautions to be taken in handling and storing: Do not store above 30°C (86°F).

Other Precautions: NONE

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle in a well-ventilated area.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Necessary clothing to prevent skin contact such as lab coat with closed front, long sleeves or elastic cuffs.

Work/Hygienic Practices: Wash hands following use. No eating, drinking or smoking when handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid

Appearance and Odor: White powder
with no odor

Boiling Point: Not Applicable

Vapor Pressure: Not Applicable

Vapor Density: Not Applicable

Specific Gravity: Not Applicable

Melting Point: Not Available

Evaporation Rate: Not Applicable

Solubility in Water: Soluble in water

pH: 6.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Conditions to Avoid: Store away from strong oxidizers.

Incompatibility (Materials to Avoid): Strong oxidizers or water reactive materials.

Hazardous Decomposition or Byproducts: When heated, products of combustion may include nitrogen oxides, hydrogen chloride, carbon monoxide and carbon dioxide.

Hazardous Polymerization: Will not occur.

Section XI - TOXICOLOGICAL INFORMATION

For Pamidronate Disodium: RTECS # SZ6525000

LD₅₀ mice, oral = 625 mg/kg

TD_{LO} rats, oral = 1740 mg/kg

LD₅₀ mouse, intravenous = 45 mg/kg

LD₅₀ rat, intravenous = 50 mg/kg

LD₅₀ mouse, intraperitoneal = 190 mg/kg

LD₅₀ rabbits, oral = 820 mg/kg

Carcinogenicity has not been observed in rat and mice studies. Pamidronate is negative for mutagenicity in Ames test, Salmonella and Escherichia liver-microsome test, nucleus-anomaly test and rat micronucleus test.

Section XII - ENVIRONMENTAL IMPACT INFORMATION

For active ingredient Pamidronate Disodium:

Acute Toxicity to Invertebrates: *Daphnia magna*, 48 hour static acute, NOEC = 15 mg/L

Microbial growth inhibition:

<u>Species</u>	<u>Minimum Inhibitory Concentration</u> <u>(mg/L)</u>
<i>Aspergillus niger</i>	> 1000
<i>Trichoderma viride</i>	> 1000
<i>Clostridium perfringens</i>	200
<i>Bacillus subtilis</i>	200
<i>Nostoc</i> sp.	> 1000

Section XIII - DISPOSAL INFORMATION

Dispose of via incineration at an approved, permitted waste disposal facility according to state, federal and local guidelines.

Section XIV - TRANSPORTATION INFORMATION

Pamidronate is not a D.O.T. hazardous material.
Pamidronate is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2 = Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic
4. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

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