



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road **Emergency Telephone** **(800) 551-7176**
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Product Identifier: Pamidronate Disodium Injection
Chemical Name: Pamidronate Disodium
Category: Bone Resorption Inhibitor

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Pamidronate Disodium	57248-88-1	3 mg/mL or 9 mg/mL
Mannitol	69-65-8	47 mg/mL or 37.5 mg/mL
Water for Injection	7732-18-5	QS

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listing as Carcinogen

NTP: No

IARC: No

OSHA: No

Note: NA

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.

Skin: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

SECTION 4 - EMERGENCY & FIRST AID MEASURES...continued

Ingestion: Flush mouth out with water immediately. Seek medical attention.
Contact Info: For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point: NE

Open Cup Flash Point: NE

Fire Point: NE

Autoignition: NE

Lower Explosion Limit: NE

Upper Explosion Limit: NE

General Hazard: No unusual fire or explosion hazard is known to exist.

Fire Fighting Instructions: Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.

Fire Fighting Equipment: Wear self-containing breathing apparatus and protective clothing.

Hazardous Combustion Products: Thermal decomposition may yield carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.

SECTION 7 - HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Store at controlled room temperature 15°-30°C (59°-86°F).

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

Personal Protective Equipment

Eye Protection: Safety glasses or goggles recommended.

Hand Protection: Disposable latex gloves recommended.

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Pamidronate Disodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance: Sterile aqueous solution

Boiling Point/Boiling Range: NE

Melting Point/Melting Range: NE

Freezing Point: NE

Vapor Pressure : NE

Relative Vapor Density: NE

Percent Volatiles: NE

pH: 6.5

Molecular Weight: 279.03

Solvent Solubility: Soluble in water

Note: NA

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable under most conditions.
Conditions to Avoid: Avoid contact with oxidizing agents.
Hazardous Polymerization: Not known to occur.

SECTION 11 - TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure: 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. Adverse reactions from therapeutic doses include: osteonecrosis of the jaw, renal insufficiency, elevation of temperature, local soft-tissue symptoms (redness, swelling, induration, pain), seizures, fluid overload, generalized pain, hypertension, abdominal pain, anorexia, constipation, urinary tract infection, bone pain, anemia, hypokalemia, hypomagnesemia, and hypophosphatemia. Occupational exposure has not been fully investigated.

Medical Conditions Aggravated by Accidental Exposure: Individuals with clinically significant hypersensitivity to Pamidronate Disodium Injection or other bisphosphonates.

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Pamidronate Disodium	LD ₅₀	Oral	Male Mice	680 mg/kg
	LD ₅₀	Oral	Female Mice	1000 mg/kg
	LD ₅₀	Oral	Rat	1560 mg/kg
	LD ₅₀	Oral	Rabbit	820 mg/kg
	LD ₅₀	IV	Rat	50 mg/kg
	LD ₅₀	IP	Mouse	190 mg/kg
	LD ₅₀	IV	Mouse	45 mg/kg

Other: PREGNANCY CATEGORY C:
There are no adequate and well-controlled studies in pregnancy women.

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number: NA
U.S. DOT Hazard Class: NA
Proper Shipping Name: NA
Shipping Label: NA

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure : Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

SECTION 14 - OTHER

Key to Abbreviations: ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

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