SAFETY DATA SHEET

Product Name: Pamidronate Disodium Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Names And Addresses	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418	
Hospira, Inc., Non-Emergency	224 212-2000	
Material Name	Pamidronate Disodium Injection	
Synonyms	Phosphonic acid (3-amino-1-hydroxypropylidene)bis-, disodium salt; Disodium 3-amino-1-hydroxypropylidene-1,1-biphosphate; Disodium Pamidronate.	

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Pamidronate Disodium Injection is a solution containing pamidronate disodium, a bisphosphonate which inhibits bone resorption. Clinically, pamidronate disodium is used to treat severe hypercalcemia associated with malignancy, osteolytic lesions and bone pain in multiple myeloma, or bone metastases associated with breast cancer. In the workplace, this material should be considered a potent drug, potentially irritating to the skin, eyes and respiratory tract, and a potential occupational reproductive hazard. Based on clinical use, possible target organs may include the skeletal system, gastrointestinal system, cardiovascular system, central nervous system, blood, and kidneys.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified
Health Hazards	**Hazard Class**	**Hazard Category**
	Toxic to Reproduction	2

Label Element(s)

Pictogram

Signal Word: Warning

Hazard Statement(s): Suspected of damaging fertility or the unborn child

Precautionary Statement(s)

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Pamidronate Disodium
Chemical Formula $C_3H_9NO_7P_2Na_2$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Pamidronate Disodium	0.3-0.9	57248-88-1	SZ6525000

Non-hazardous ingredients include Water for Injection and mannitol. Hazardous ingredients present at less than 1% include phosphoric acid and/or sodium hydroxide which are added to adjust the pH.

4. FIRST AID MEASURES

Eye Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Put on suitable protective clothing and equipment as specified by site spill control procedures. Isolate and contain the area around the spill. Absorb spilled liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required for hazard control under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions Persons with a known allergy to pamidronate disodium or other bisphosphonates, women who are pregnant, or women who want to become pregnant, should consult a health or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Pamidronate Disodium	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Skin Protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Eye Protection	As a minimum, the use of chemical safety goggles is recommended when handling this material.
Engineering Controls	If the generation of aerosols is likely, local exhaust ventilation is recommended to minimize employee exposure. If available, the use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is also recommended.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	A clear colorless aqueous solution
Odor	NA
Odor Threshold	NA
pH	6.0-7.0
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Pamidronate disodium is soluble in water and in 2N sodium hydroxide, sparingly soluble in 0.1N hydrochloric acid and in 0.1N acetic acid, and practically insoluble in organic solvents.
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	NA
Chemical Stability	Stable under recommended storage conditions and use.
Hazardous Reactions	NA
Conditions to Avoid	NA
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sodium oxides (NaOx) and phosphorus oxides (POx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - No data found for the formulated product. Information for the active ingredient follows.

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Pamidronate Disodium	100	LD50	Oral	625	mg/kg	Mouse
*Pamidronate Disodium	100	LD50	Oral	1560	mg/kg	Rat
*Pamidronate Disodium	100	LD50	Oral	680	mg/kg	Mice, male
*Pamidronate Disodium	100	LD50	Oral	1000	mg/kg	Mice, female
*Pamidronate Disodium	100	LD50	Oral	820	mg/kg	Rabbit
Pamidronate Disodium	100	LD50	Intravenous	50	mg/kg	Rat
Pamidronate Disodium	100	LD50	Intravenous	45	mg/kg	Mouse
Pamidronate Disodium	100	LD50	Intravenous	190	mg/kg	Mouse

LD50 is the dosage producing 50% mortality.
* Bedford Laboratories MSDS

Occupational Exposure Potential	Potential occupational routes of exposure may include the skin, eyes, and respiratory tract. Avoid the generation of aerosols, and inadvertent contact with the skin, eyes, or mucus membranes. Where possible, engineering controls should be utilized to control potential exposures to the aerosolized product.
Signs and Symptoms	None anticipated from normal handling of this product. This product may be irritating to the skin, eyes, respiratory tract, and mucus membranes. By analogy, in clinical use, pamidronate disodium may produce fever, gastrointestinal disturbances (abdominal pain, anorexia, constipation, nausea, vomiting) and hematological abnormalities (anemia, thrombocytopenia, and lymphocytopenia). Flu-like symptoms (malaise, rigors, fatigue, and flushes) are common during intravenous infusion of pamidronate but generally resolve spontaneously. Tenderness at the infusion site has also been reported. Like other bisphosphonates, pamidronate may cause nephrotoxicity. Central nervous system (CNS) effects may include agitation, confusion, dizziness, lethargy, insomnia, and somnolence. Atrial fibrillation, tachycardia, and both hypotension and hypertension have also been reported. Bronchospasm and interstitial pneumonitis have occurred rarely.

11. TOXICOLOGICAL INFORMATION: continued

Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product. Pamidronate disodium is reported to be moderately irritating to the skin in a skin irritation study in animals. Inadvertent skin contact with this product may produce irritation and redness.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. Pamidronate disodium is reported to be severely irritating to the eyes in an eye irritation study in animals. Inadvertent eye contact with this product may produce irritation with redness and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. In clinical use, rare occurrences of allergic manifestations have been reported for pamidronate disodium, including hypotension, dyspnea, or angioedema, and, very rarely, anaphylactic shock.
Reproductive Effects	None anticipated from normal handling of this product. In rats, decreased fertility occurred in first-generation offspring of parental animals that were treated orally with 150 mg/kg/day of pamidronate. Bolus intravenous studies conducted in rats and rabbits resulted in maternal toxicity and embryo/fetal effects. Administration of pamidronate to rats and rabbits either orally at a dosage of 150 mg/kg, or intravenously at dosages of 6 to 15 mg/kg during organogenesis produced delayed ossification. Pamidronate given intravenously to rats produced a shortening of long bones at dosages of 12-15 mg/kg; other findings included dilated renal pelvices and ureters.
Mutagenicity	Pamidronate was nonmutagenic in a battery of mutagenicity assays including the Ames test, *Salmonella* and *Escherichia*/liver-microsome test, nucleus-anomaly test, sister-chromatid-exchange study, point-mutation test, and a micronucleus test in the rat.
Carcinogenicity	Pamidronate disodium produced a dose-related increase in benign adrenal pheochromocytoma in male rats in a 104-week oral-dose carcinogenicity study in rats. Similar, but not statistically significant findings were noted in females. Adrenal pheochromocytoma was also observed in low numbers in the control animals and is considered a relatively common spontaneous neoplasm in the rat. In a similar study, daily oral administration of pamidronate was not carcinogenic in an 80-week study in mice.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs may include the skeletal system, gastrointestinal system, cardiovascular system, central nervous system, blood, and kidneys.

12. ECOLOGICAL INFORMATION

***Aquatic Toxicity**	Not determined for product. For pamidronate disodium, the no-observed-effect concentration (NOEC) = 15 mg/L in Daphnia magna (48-hour acute, static exposure). MIC > 200 mg/L in a battery of microbial organisms for pamidronate sodium.
***Persistence/ Biodegradability**	Not determined for product. Pamidronate disodium degraded significantly in activated sewage sludge over a period of 14-21 days, with an estimated half-life of 9.9 days. This material is not anticipated to persist in the aquatic environment.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

*Teva Sicor MSDS

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

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.

15. REGULATORY INFORMATION: continued

EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator:	Hospira GEHS
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