



A Pfizer Company

SAFETY DATA SHEET

Revision date: 30-Mar-2017

Version: 3.1

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Pamidronate Disodium Injection (Hospira, Inc.)

Trade Name: Not applicable
Synonyms: PAMISOL
Chemical Family: Bisphosphonate

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Label Elements

Signal Word: Danger
Hazard Statements: H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Pamidronate disodium	57248-88-1	260-647-1	Acute Tox. 4 (H302) Repr.1B (H360FD) Eye Irrit. 2A (H319) Skin Irrit. 2 (H315)	0.3-0.9
Phosphoric acid	7664-38-2	231-633-2	Skin Corr. 1B (H314)	**
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Phosphoric acid

ACGIH Threshold Limit Value (TWA)	1 mg/m ³
ACGIH Threshold Limit Value (STEL)	3 mg/m ³
Australia STEL	3 mg/m ³
Australia TWA	1 mg/m ³
Austria OEL - MAKs	1 mg/m ³
Belgium OEL - TWA	1 mg/m ³
Bulgaria OEL - TWA	1.0 mg/m ³
Cyprus OEL - TWA	1 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Denmark OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
Finland OEL - TWA	1 mg/m ³
France OEL - TWA	0.2 ppm 1 mg/m ³
Germany - TRGS 900 - TWAs	2 mg/m ³
Germany (DFG) - MAK	2 mg/m ³
Greece OEL - TWA	1 mg/m ³
Hungary OEL - TWA	1 mg/m ³
Ireland OEL - TWAs	1 mg/m ³
Italy OEL - TWA	1 mg/m ³
Latvia OEL - TWA	1 mg/m ³
Lithuania OEL - TWA	1 mg/m ³
Luxembourg OEL - TWA	1 mg/m ³
Malta OEL - TWA	1 mg/m ³
Netherlands OEL - TWA	1 mg/m ³
OSHA - Final PELs - TWAs:	1 mg/m ³
Poland OEL - TWA	1 mg/m ³
Portugal OEL - TWA	1 mg/m ³
Romania OEL - TWA	1 mg/m ³
Slovakia OEL - TWA	1 mg/m ³
Slovenia OEL - TWA	1 mg/m ³
Spain OEL - TWA	1 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	1 mg/m ³
Vietnam OEL - TWAs	1 mg/m ³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³

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Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Pamidronate disodium

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	6.0-7.4		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			

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9. PHYSICAL AND CHEMICAL PROPERTIES

Mannitol

No data available

Water for injection

No data available

Pamidronate disodium

No data available

SODIUM HYDROXIDE

No data available

Phosphoric acid

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye and skin irritation (based on components) .

Known Clinical Effects: Common adverse effects include fever, bone pain, back pain, vomiting, decreased red blood cell count (anemia), electrolyte imbalance and kidney effects.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

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11. TOXICOLOGICAL INFORMATION

Pamidronate disodium

Rat Oral LD50 1560 mg/kg

Mouse Oral LD50 625mg/kg

Rat IV LD50 50mg/kg

Phosphoric acid

Rat Oral LD50 1530 mg/kg

Rabbit Dermal LD 50 2730mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Pamidronate disodium

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Phosphoric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Pamidronate disodium

3 Month(s) Dog IV infusion 2 mg/kg/week NOAEL Kidney

3 Month(s) Rat IV infusion 2 mg/kg/week NOAEL Kidney

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pamidronate disodium

Embryo / Fetal Development Rat Oral 150 mg/kg/day LOAEL Developmental toxicity

Embryo / Fetal Development Rabbit Oral 150 mg/kg/day LOAEL Developmental toxicity, Maternal Toxicity

Embryo / Fetal Development Rat Intravenous 6 mg/kg/day LOAEL Developmental toxicity, Maternal Toxicity

2 Generation Reproductive Toxicity Rat Oral 150 mg/kg/day LOAEL Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Pamidronate disodium

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Sister Chromatid Exchange Not specified Negative

Micronucleus Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pamidronate disodium

80 Week(s) Mouse Oral Not specified NOAEL Not carcinogenic

104 Week(s) Rat Oral Not specified Benign tumors

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Pamidronate disodium

Daphnia magna (Water Flea) NOEC 48 Hours 15 mg/L

Phosphoric acid

Gambusia affinis (Mosquitofish) LC50 96 Hours 3-3.5 mg/L

Daphnia magna (Water Flea) EC-50 12 Hours 4.6 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Pamidronate disodium

Aspergillus niger (Fungus) > 1000 mg/L

Bacillus subtilis (Bacterium) MIC 200 mg/L

Clostridium perfringens (Bacterium) MIC 200 mg/L

Nostoc sp. (Freshwater Cyanobacteria) MIC >1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Pamidronate disodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	260-647-1

Mannitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Phosphoric acid

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-633-2

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet