SAFETY DATA SHEET

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

Contact E-Mail: pfizer-MSDS@pfizer.com

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
3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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.
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.

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
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

**Phosphoric acid**

- ACGIH Threshold Limit Value (TWA): 1 mg/m³
- ACGIH Threshold Limit Value (STEL): 3 mg/m³
- Australia STEL: 3 mg/m³
- Australia TWA: 1 mg/m³
- Austria OEL - MAKs: 1 mg/m³
- Belgium OEL - TWA: 1 mg/m³
- Bulgaria OEL - TWA: 1.0 mg/m³
- Cyprus OEL - TWA: 1 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Denmark OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
- Finland OEL - TWA: 1 mg/m³
- France OEL - TWA: 0.2 ppm
- Germany - TRGS 900 - TWAs: 2 mg/m³
- Germany (DFG) - MAK: 2 mg/m³
- Greece OEL - TWA: 1 mg/m³
- Hungary OEL - TWA: 1 mg/m³
- Ireland OEL - TWAs: 1 mg/m³
- Italy OEL - TWA: 1 mg/m³
- Latvia OEL - TWA: 1 mg/m³
- Lithuania OEL - TWA: 1 mg/m³
- Luxembourg OEL - TWA: 1 mg/m³
- Malta OEL - TWA: 1 mg/m³
- Netherlands OEL - TWA: 1 mg/m³
- OSHA - Final PELS - TWAs: 1 mg/m³
- Poland OEL - TWA: 1 mg/m³
- Portugal OEL - TWA: 1 mg/m³
- Romania OEL - TWA: 1 mg/m³
- Slovakia OEL - TWA: 1 mg/m³
- Slovenia OEL - TWA: 1 mg/m³
- Spain OEL - TWA: 1 mg/m³
- Sweden OEL - TWAs: 1 mg/m³
- Switzerland OEL - TWAs: 1 mg/m³
- Vietnam OEL - TWAs: 1 mg/m³

**SODIUM HYDROXIDE**

- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Bulgaria OEL - TWA: 2.0 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
- France OEL - TWA: 2 mg/m³
- Greece OEL - TWA: 2 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Japan - OELs - Ceilings: 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Substance</th>
<th>OEL (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>2</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Solution</td>
</tr>
<tr>
<td>Color:</td>
<td>Clear, colorless</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>6.0-7.4</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient:</td>
<td>(Method, pH, Endpoint, Value)</td>
</tr>
</tbody>
</table>
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

PZ01430
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.
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 perfingens (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.
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
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.

Revision date: 30-Mar-2017


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