# SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Product Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Material Name:</strong> NIPENT® (pentostatin for injection) (Hospira Inc.)</td>
</tr>
<tr>
<td><strong>Trade Name:</strong> Nipent</td>
</tr>
<tr>
<td><strong>Chemical Family:</strong> Mixture</td>
</tr>
</tbody>
</table>

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

**Intended Use:** Pharmaceutical product used as Antineoplastic

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

- **GHS - Classification**
  - Acute Oral Toxicity: Category 4
  - Germ Cell Mutagenicity: Category 2
  - Reproductive Toxicity: Category 1B

### Label Elements

- **Signal Word:** Danger
- **Hazard Statements:**
  - H302 - Harmful if swallowed
  - H341 - Suspected of causing genetic defects
  - H360D - May damage the unborn child

- **Precautionary Statements:**
  - P201 - Obtain special instructions before use
  - P264 - Wash hands thoroughly after handling
  - P270 - Do not eat, drink or smoke when using this product
  - P281 - Use personal protective equipment as required
  - P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
  - 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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**Hospira, A Pfizer Company**

275 North Field Drive

Lake Forest, Illinois 60045

1-800-879-3477

**Contact E-Mail:** pfizer-MSDS@pfizer.com
Other Hazards
Note: No data available
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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentostatin</td>
<td>53910-25-1</td>
<td>Not Listed</td>
<td>Acute Tox.3 (H301) Repr.1B (H360D) Muta.2 (H341)</td>
<td>10-20</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)</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: * Proprietary  ** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. 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
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: 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
Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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 used as Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK: 5 ppm
7.5 mg/m^3
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Unit 1</th>
<th>Unit 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm</td>
<td>7.6 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
</tbody>
</table>

**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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Safety Data Sheet</th>
<th>Exposures Controls</th>
<th>Personal Protective Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Engineering Controls:</strong></td>
<td>Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.</td>
<td></td>
</tr>
<tr>
<td><strong>Hands:</strong></td>
<td>Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.)</td>
<td></td>
</tr>
<tr>
<td><strong>Eyes:</strong></td>
<td>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.)</td>
<td></td>
</tr>
<tr>
<td><strong>Skin:</strong></td>
<td>Impervious disposable 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.)</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory protection:</strong></td>
<td>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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)</td>
<td></td>
</tr>
</tbody>
</table>

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Lyophilized powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>Soluble Water</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>220 - 225</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Mannitol</td>
</tr>
<tr>
<td></td>
<td>No data available.</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Sodium hydroxide
No data available

Hydrochloric Acid
No data available

Pentostatin
Predicted 7.4 Log D -3.811

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. As a precautionary measure, keep away from heat sources and electrostatic discharge.
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.
Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. Occasional, transient changes reported in liver function tests, but no liver damage seen. Kidney dysfunction has been seen during clinical use.

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

Mannitol
<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>13500 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>22 g/kg</td>
</tr>
</tbody>
</table>

Sodium hydroxide
<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>IP</td>
<td>LD50</td>
<td>40 mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Pentostatin
Mouse  Oral  LD 50  227 mg/kg
Mouse  Para-periosteal  LD 50  122mg/kg

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

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

Hydrochloric Acid
Skin Irritation  Severe
Eye Irritation  Severe

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

Pentostatin
5 Day(s)  Dog  Intravenous  1 mg/kg/day  LOAEL  Male reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Pentostatin
Embryo / Fetal Development  Rat  Intravenous  0.05 mg/kg/day  LOAEL  Teratogenic
Embryo / Fetal Development  Mouse  Intraperitoneal  2 mg/kg/day  LOAEL  Teratogenic
Embryo / Fetal Development  Rat  Intravenous  0.1 mg/kg/day  LOAEL  Maternal Toxicity, Teratogenic
Embryo / Fetal Development  Rabbit  Intravenous  0.005 mg/kg/day  LOAEL  Maternal Toxicity, Embryotoxicity

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

Pentostatin
Bacterial Mutagenicity (Ames)  Salmonella  Positive
In Vivo Micronucleus  Mouse Bone Marrow  Positive
Mammalian Cell Mutagenicity  Hamster HGPRT  Negative
Chromosome Aberration  Hamster HGPRT  Negative

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Hydrochloric Acid
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:  No data available
Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Pentostatin
Predicted  7.4  Log D  -3.811

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

Pentostatin
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: developmental toxicity 9/1/1996
- EU EINECS/ELINCS List: Not Listed

Hydrochloric Acid
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 5000 lb
  - 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
SAFETY DATA SHEET

Material Name: NIPENT® (pentostatin for injection) (Hospira Inc.)
Revision date: 01-Aug-2016

15. REGULATORY INFORMATION

| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 5000 lb |
| 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 |
| EU EINECS/ELINCS List | 231-595-7 |

Sodium hydroxide

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 1000 lb |
| 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 |
| EU EINECS/ELINCS List | 215-185-5 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Revision date: 01-Aug-2016
Prepared by: Product Stewardship Hazard Communication

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