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

Material Name: Pentostatin Powder for Injection

Trade Name: Nipent
Chemical Family: Mixture
Intended Use: Antineoplastic

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Material Name: Pentostatin Powder for Injection

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>**</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>**</td>
</tr>
<tr>
<td>Pentostatin</td>
<td>53910-25-1</td>
<td>Not listed</td>
<td>16.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</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.

3. HAZARDS IDENTIFICATION

Appearance: Lyophilised powder
Signal Word: WARNING

Statement of Hazard:
Harmful if swallowed.
May cause harm to the unborn child.
Possible mutagen

Additional Hazard Information:
Short Term: Harmful if swallowed (based on animal data).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus.

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.
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic Category 3

EU Hazard Symbols:

EU Risk Phrases: R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

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

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store in a refrigerator before reconstitution.

Storage Temperature: 2-8°C (36-46°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
Australia PEAK = 7.5 mg/m³ Peak

Sodium hydroxide

OSHA - Final PELS - TWAs: = 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak

Engineering Controls: 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.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Lyophilized powder
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
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.
11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Pentostatin
Mouse  Oral  LD 50  227 mg/kg
Mouse  Intravenous  LD 50  122 mg/kg

Mannitol
Rat  Oral  LD 50  13500 mg/kg
Mouse  Oral  LD 50  22 g/kg

Sodium hydroxide
Mouse  IP  LD50  40 mg/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
12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic Category 3

EU Risk Phrases: R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases: S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Harmful if swallowed.
May cause harm to the unborn child.
Possible mutagen

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials
16. OTHER INFORMATION

Reasons for Revision:
Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations.

Prepared by:
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet