



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

Page 1 of 6

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Pentostatin Powder for Injection**

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

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydrochloric Acid	7647-01-0	231-595-7	**
Sodium hydroxide	1310-73-2	215-185-5	**
Pentostatin	53910-25-1	Not listed	16.6

Ingredient	CAS Number	EU EINECS List	%
Mannitol	69-65-8	200-711-8	*

**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.

## MATERIAL SAFETY DATA SHEET

Material Name: Pentostatin Powder for Injection  
Revision date: 04-Jan-2007

Page 2 of 6  
Version: 1.1

**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.

## MATERIAL SAFETY DATA SHEET

Material Name: Pentostatin Powder for Injection  
Revision date: 04-Jan-2007

Page 3 of 6  
Version: 1.1

**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  
= 7.5 mg/m<sup>3</sup> Peak

#### Sodium hydroxide

**OSHA - Final PELs - TWAs:** 2 mg/m<sup>3</sup>  
**ACGIH Ceiling Threshold Limit:** = 2 mg/m<sup>3</sup> Ceiling  
**Australia PEAK** = 2 mg/m<sup>3</sup> 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:

<b>Physical State:</b>	Lyophilized powder	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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.

## MATERIAL SAFETY DATA SHEET

Material Name: Pentostatin Powder for Injection  
Revision date: 04-Jan-2007

Page 4 of 6  
Version: 1.1

### 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 LOEL 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 LOEL Teratogenic  
Embryo / Fetal Development Mouse Intraperitoneal 2 mg/kg/day LOEL Teratogenic  
Embryo / Fetal Development Rat Intravenous 0.1 mg/kg/day LOEL Maternal Toxicity, Teratogenic  
Embryo / Fetal Development Rabbit Intravenous 0.005 mg/kg/day LOEL 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

## MATERIAL SAFETY DATA SHEET

Material Name: Pentostatin Powder for Injection  
Revision date: 04-Jan-2007

Page 5 of 6  
Version: 1.1

### 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



# MATERIAL SAFETY DATA SHEET

Material Name: Pentostatin Powder for Injection  
Revision date: 04-Jan-2007

Page 6 of 6  
Version: 1.1

## Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	231-595-7

## Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

## Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
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 List	215-185-5

## Pentostatin

California Proposition 65	developmental toxicity, initial date 9/1/96
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## 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