# Material Safety Data Sheet

## Section 1. Product Identification

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|---|---|
| Common Name/Trade Name | **Nipent** ® |
| How supplied | single-dose vials |
| Manufacturer / Supplier | SuperGen, Inc.<br>4140 Dublin Blvd., Suite 200<br>Dublin, CA 94568 |
| Company Contact | Joi Ninomoto<br>(925) 560-0100 |
| Emergency phone | (800) 353-1075 |
| Synonyms | pentostatin for Injection, 10 mg |
| NDC# | 00714243 |

## Section 2. Composition and Information on Ingredients

| | | | Exposure Limits | |
|---|---|---|---|---|
| Name | CAS # | % by Weight | OSHA PEL | ACGIH TLV |
| Mannitol | 69-65-8 | 83 % | | |
| Pentostatin | 53910-25-1 | 17 % | ND | ND |

## Section 3. Hazards Identification

**Potential Health Effects**

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| Therapeutic Class | Anticancer, Adenosine deaminase inhibitor |
| **Primary Routes of Entry** | Injection into the skin; Ingestion |
| **Signs and Symptoms of Overexposure** | Acute Effects: ND<br>Chronic Effects: ND |

## Section 4. First Aid Measures

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| Eyes | Flush with water for 15 minutes. Seek medical help. |
| Inhalation | Remove to fresh air, seek medical attention. |
| Skin | Flush with water for 15 minutes. Wash with soap and water until free of residue. |
| Ingestion | Give moderate amounts of water. Seek prompt medical attention. |
| Accidental Injection | Seek prompt medical attention |

## Section 5. Fire and Explosion Data

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|---|---|
| Flash point and method | ND |
| Extinguishing medium | $CO_2$, Dry Chem, Water Spray. This material does not support combustion. |
| Special Fire Fighting Procedures | Use NIOSH/MSHA approved self-contained breathing apparatus. |
| Hazardous Decomposition Or Combustion Products | Oxides of carbon and nitrogen |
| Unusual Fire Hazards | ND |
| Unusual Explosion Hazards | NA |

## Section 6. Accidental Release Measures

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| Spill | Prevent exposure. Contain the spill. Use wet clean up method with appropriate solvent such as water. An industrial vacuum cleaner equipped with high efficiency particulate filter can be used. Absorb spilled material with an inert ingredient such as sand or vermiculite and place inappropriate container. Use care in the cleanup of broken glass. Decontaminate by soaking area with a 10% Sodium hypochlorite solution for 30 minutes. Place waste in appropriate container(s) for future disposal. |

## Section 7. Handling and Storage

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| Storage | Store as stated in product labeling. |

## Section 8. Exposure Controls/Personal Protection

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| Engineering Controls | General ventilation |
| Personal Protection | Material should be handled in such a way as to avoid skin and eye contact. Exercise caution when purging air from the administration system. Hand and eye protection is recommended. If contact should occur, wash contaminated skin promptly. Launder contaminated clothing and clean protective equipment before reuse.<br><br>Refer to "Preparation of Intravenous Solution" section of current package insert for specific information. |

## Section 9. Physical and Chemical Properties

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| Physical State and Appearance | Bulk Solution: Liquid; clear, colorless to pale yellow, Aqueous<br>Filled Vials: Powder; solid white to off-white cake or powder |
| pH (@ 25ºC) | Bulk Solution: Between 7.8 – 8.2<br>Filled Vials: Between 7.0 – 8.5 |
| Odor Threshold | ND |
| Specific Gravity (water=1) | ND |
| Solubility (water) | ND |
| Solubility (pH 9 borate buffer) | ND |
| Melting point | ND |
| Boiling point | NA |
| Vapor Pressure | NA |
| Vapor Density | NA |

## Section 10. Stability and Reactivity Data

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|---|---|
| Stability and Polymerization | Under normal storage conditions, this product is stable and hazardous polymerization should not occur. |

## Section 11. Toxicological Information

**The following information pertains to the ingredient(s) individually and not to the product as marketed. Included will be any data which emphasize the potential effects that may occur with the occupational handling (by inhalation or by dermal or ocular contact) of this product.**

| | |
|---|---|
| Pentostatin | Mouse I.V. $LD_{50}$ = 128 mg/kg; I.P. $LD_{50}$ = 7.2 mg/kg<br><br>Short-term studies in mice showed hepatotoxicity and lymphopenia. Dogs given pentostatin developed lymphopenia, thrombocytopenia, reticulocytopenia, leucocytosis, and elevated serum liver enzymes. Not mutagenic in Ames mutagenicity assay with or without metabolic activation. Embryotoxic in mice. Induced chromosomal damage to human lymphocytes in culture. Treatment in humans has been associated with immunosupression and the resulting infectious complications-reduced white blood cells (lymphopenia), nausea with or without vomiting, lethargy, keratoconjunctivitis and rashes. |

(See current package insert for further information)

## Section 12. Ecological Information

ND

## Section 13. Disposal Considerations

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| Waste Disposal | Dispose of in accordance with local, state and federal regulations or the authority having jurisdiction. Incineration in a permitted incinerator is the preferred disposal method. |

## Section 14. Transport Information

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| Proper Shipping Name | Consumer Commodity (surface)<br>Dangerous Goods in Excepted Quantity (air) |
| Hazard Class | ORM-D (surface)<br>6.1 (air) |
| ID/UN Number | NA (surface)<br>3249 or 2811 (air) |
| Label | NA (surface)<br>Dangerous Goods in Excepted Quantity (air) |
| Packing Group | III |
| Shipping limitations | 30 grams Inner Vial (air)<br>1 kg Maximum Net Quantity (air) |

## Section 15. Regulatory Information

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|---|---|
| US Federal and State Regulations | Chronic Toxic |
| OSHA Hazardous Communication Label | Hematoxic |
| California Proposition 65 Warnings | WARNING: This product contains a chemical known to the State of California to cause cancer.<br>Chemical ingredient(s) requiring this warning:<br>None<br><br>WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.<br>Chemical ingredient(s) requiring this warning:<br>Pentostatin |
| Other Classifications | National Fire Protection Association (U.S.A)<br>HEALTH: 2 FLAMMABLE: 0 REACTIVITY: 0 |

## Section 16. Other Information

The information contained within this Material Safety Data Sheet (MSDS) is based on currently available scientific studies and is accurate and reliable to the best of our knowledge. SuperGen, Inc. makes no warranties, expressed or implied, and assumes no responsibility or liability for any damage or injuries of any kind which may result from use or reliance upon this information.

Prepared By: *Susan M. Iovino* Date: October 28, 1999

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APPROVED BY: *Ashok Gore*