



Material Safety Data Sheet

Section 1. Product Identification

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

Section 2. Composition and Information on Ingredients

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

Section 3. Hazards Identification

Potential Health Effects

Therapeutic Class Anticancer, Adenosine deaminase inhibitor

Primary Routes of Entry Injection into the skin; Ingestion

Signs and Symptoms of Overexposure Acute Effects: ND
Chronic Effects: ND

Section 4. First Aid Measures

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

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

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 in appropriate 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

Storage	Store as stated in product labeling.
---------	--------------------------------------

Section 8. Exposure Controls/Personal Protection

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.
	Refer to "Preparation of Intravenous Solution" section of current package insert for specific information.

Section 9. Physical and Chemical Properties

Physical State and Appearance	Bulk Solution: Liquid; clear, colorless to pale yellow, Aqueous Filled Vials: Powder; solid white to off-white cake or powder
pH (@ 25°C)	Bulk Solution: Between 7.8 – 8.2 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

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. LD₅₀ = 128 mg/kg; I.P. LD₅₀ = 7.2 mg/kg

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 immunosuppression 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

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

Proper Shipping Name

Consumer Commodity (surface)
Dangerous Goods in Excepted Quantity (air)

Hazard Class

ORM-D (surface)
6.1 (air)

ID/UN Number

NA (surface)
3249 or 2811 (air)

Label

NA (surface)
Dangerous Goods in Excepted Quantity (air)

Packing Group

III

Shipping limitations

30 grams Inner Vial (air)
1 kg Maximum Net Quantity (air)

Section 15. Regulatory Information

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. Chemical ingredient(s) requiring this warning: None
	WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. Chemical ingredient(s) requiring this warning: Pentostatin
Other Classifications	National Fire Protection Association (U.S.A) 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

MSDS No.: 102 Revision No.: New Revised Date: _____

APPROVED BY: Ashok Gore