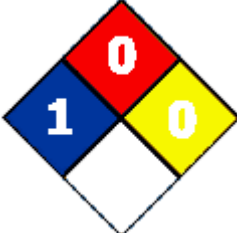


NFPA	HMIS	PPE	Transport Symbol						
	<table border="1"> <tr> <td>Health Hazard</td> <td style="text-align: center;">1</td> </tr> <tr> <td>Fire Hazard</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Reactivity</td> <td style="text-align: center;">0</td> </tr> </table>	Health Hazard	1	Fire Hazard	0	Reactivity	0		
Health Hazard	1								
Fire Hazard	0								
Reactivity	0								

Chronic Hazard Star Legend

Issuing Date 21-May-2009

Revision Date

Revision Number 0

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name NICARDipine Hydrochloride Injection

Product Code(s) 10139-700-10 - 10 mL Vial
10139-700-11 - Shelf Pack (10 mL Vials X 10)

Recommended Use Calcium channel blocker

Supplier Address GeneraMedix Inc.
150 Allen Road
Liberty Corner, New Jersey 07938, USA
TEL: 908-504-1300

Chemical Emergency Phone Number Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Emergency Overview

Irritating to eyes.

Appearance Clear, Yellow

Physical State Liquid

Odor No data available.

Potential Health Effects

Principle Routes of Exposure

Inhalation. Skin contact. Eye contact.

Acute Toxicity

Eyes

Irritating to eyes.

Skin

May cause skin irritation and/or dermatitis.

Inhalation

Not an expected route of exposure. Inhalation of aerosols: May cause irritation of respiratory tract.

Ingestion

May be harmful if swallowed. May cause gastrointestinal discomfort if consumed in large amounts.

Chronic Effects

None known.

Aggravated Medical Conditions

None known.

Environmental Hazard

See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Water for Injection	7732-18-5	~95
Sorbitol	50-70-4	4.8
Nicardipine HCL	54527-84-3	0.25
Citric acid	77-92-9	0.0525
Sodium hydroxide	1310-73-2	0.009

Additional citric acid and/or sodium hydroxide may be added to adjust to target pH = 3.5.

4. FIRST AID MEASURES

General Advice	Immediate medical attention is not required. Show this safety data sheet to the doctor in attendance.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.
Skin Contact	Wash off immediately with soap and plenty of water.
Inhalation	Not an expected route of exposure. Move to fresh air.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.
Notes to Physician	Treat symptomatically

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable
Flash Point	N/A
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<u>Explosion Data</u>	
Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

<u>NFPA</u>	Health Hazard 1	Flammability 0	Stability 0	Physical and Chemical Hazards N/A
<u>HMIS</u>	Health Hazard 1	Flammability 0	Stability 0	Personal Protection N/A

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Avoid contact with eyes.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Soak up with inert absorbent material. After cleaning, flush away traces with water. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Avoid contact with skin and eyes.
Storage	Store at room temperature. Keep at temperatures between 20 °C and 25 °C. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hydroxide	Ceiling: 2 mg/m ³	TWA: 2 mg/m ³ (vacated) Ceiling: 2 mg/m ³	IDLH: 10 mg/m ³ Ceiling: 2 mg/m ³

NIOSH IDLH: Immediately Dangerous to Life or Health

Engineering Measures	Showers, eyewash stations, and ventilation systems
Personal Protective Equipment	
Eye/Face Protection	Safety glasses with side-shields.
Skin and Body Protection	Lightweight protective clothing.
Respiratory Protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear, Yellow	Odor	No data available.
Odor Threshold	No data available.	Physical State	Liquid
pH	3.5	Autoignition Temperature	N/A
Flash Point	N/A	Boiling Point/Range	>100°C
Decomposition Temperature	No data available.	Explosion Limits	No data available.
Melting Point/Range	No data available.	Water Solubility	Soluble in water
Flammability Limits in Air	No data available.	Vapor Pressure	No data available.
Molecular Weight	No data available.	VOC Content	N/A
Evaporation Rate	No data available.		
Vapor Density	No data available.		
Partition Coefficient (n-octanol/water)	No data available.		

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Incompatible Products	Strong oxidizing agents, Strong acids, Strong bases.
Conditions to Avoid	Excessive heat.
Hazardous Decomposition Products	None under normal use.
Hazardous Reactions	Hazardous polymerization does not occur.
Hazardous Polymerization	Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information	No acute toxicity information is available for this product.
Inhalation	Not an expected route of exposure.
Eye Contact	Irritating to eyes. Expected to be an irritant based on components
Skin Contact	Prolonged contact may cause redness and irritation.
Ingestion	Low order of toxicity based on components. Ingestion may cause irritation to mucous membranes
Other	LD50 intraperitoneal = 155 mg/kg (rat) (54527-84-3 Nicardipine HCL) LD50 intravenous = 155 mg/kg (rat) (54527-84-3 Nicardipine HCL) LD50 intraperitoneal = 123 mg/kg (mouse) (54527-84-3 Nicardipine HCL)

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Citric acid	3000 mg/kg (Rat)		
Sodium hydroxide		1350 mg/kg (Rabbit)	
Sorbitol	15900 mg/kg (Rat)		
Nicardipine HCL	184 mg/kg (Rat)		

Chronic Toxicity

Chronic Toxicity None known.

Carcinogenicity There are no known carcinogenic chemicals in this product. Rats treated with nicardipine in the diet for two years showed a dose-dependent increase in thyroid cancer. (follicular adenoma/carcinoma). Other studies in rats have suggested that these results are due to a nicardipine-induced reduction in plasma thyroxine (T4) level which can elevated thyroid stimulating hormone (TSH) levels. Chronic elevation of TSH is known to cause hyperstimulation of the thyroid.

Reproductive Toxicity

Pregnant rabbits and rats dosed with Nicardipine I.V. at doses of 1 mg/kg/day and 10 mg/kg/day respectively showed evidence of embryotoxicity, but no teratogenicity. Other feeding studies of pregnant rabbits and rats at various times during the gestation period showed no evidence of embryoletality or teratogenicity. However, dystocia, reduced birth weights, reduced neonatal survival time, and reduced neonatal weight gains were noted. There are no adequate and well-controlled studies in pregnant women. Excreted in breast milk.

Target Organ Effects

Central Vascular System (CVS), Thyroid, Reproductive system, Liver.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity Effects The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Citric acid	N/A	LC50= 1516 mg/L Lepomis macrochirus 96 h	EC50 = 14 mg/L 15 min	EC50 = 120 mg/L 72 h
Sodium hydroxide	N/A	LC50= 45.4 mg/L Oncorhynchus mykiss 96 h	N/A	N/A

Chemical Name	Log Pow
Citric acid	20

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods	This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.
Contaminated Packaging	Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated.
<u>TDG</u>	Not regulated.
<u>MEX</u>	Not regulated.
<u>ICAO</u>	Not regulated.
<u>IATA</u>	Not regulated.
<u>IMDG/IMO</u>	Not regulated.
<u>RID</u>	Not regulated.
<u>ADR</u>	Not regulated.
<u>ADN</u>	Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA	Exempt
DSL	Does not Comply
EINECS/ELINCS	Complies
ENCS	Does not Comply
IECSC	Does not Comply
KECL	Complies
PICCS	Does not Comply
AICS	Complies

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
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Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302):.

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Sodium hydroxide	1000 lb	

U.S. State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Sodium hydroxide	X	X	X	N/A	X

International Regulations

Chemical Name	Carcinogen Status	Exposure Limits
Sodium hydroxide		Mexico: Ceiling= 2 mg/m ³

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

WHMIS Hazard Class

Non-controlled. Not regulated under CEPA.

16. OTHER INFORMATION

Issuing Date	21-May-2009
Revision Date	No data available.
Revision Note	No data available.

Disclaimer

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet