

SECTION 1: IDENTIFICATION
1.1. Product Identifier

Product Form: Mixture

Product Name: Nicardipine Hydrochloride Injection

Product Code: (NDC) 0517-0735-01, 10 mL SINGLE DOSE VIAL

1.2. Intended Use of the Product

Use of the substance/mixture: The short term treatment of hypertension when oral therapy is not feasible or not desirable.

1.3. Name, Address, and Telephone of the Responsible Party
Company

American Regent , Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 CHEMTREC

SECTION 2: HAZARDS IDENTIFICATION
2.1. Classification of the Substance or Mixture
Classification (GHS-US)

Not classified

2.2. Label Elements
GHS-US Labeling

No labeling applicable

2.3. Other Hazards Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions and may affect the cardiovascular system and the central nervous system.

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	94.89	Not classified
D-Glucitol	(CAS No) 50-70-4	4.8	Comb. Dust
2-(Benzylmethylamino)ethyl methyl 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)pyridine-3,5-dicarboxylatemonohydrochloride	(CAS No) 54527-84-3	0.25	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331

Citric Acid (77-92-9) 0.05% and Sodium Hydroxide (1310-73-2) 0.01% are used for pH adjustment.

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES
4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: None expected under normal conditions of use.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

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Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Use only as directed by the information identified in the package insert.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, and spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

Storage Temperature: 20 - 25 °C (68 - 77 °F)

7.3. Specific End Use(s) The short term treatment of hypertension when oral therapy is not feasible or not desirable.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

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8.2. Exposure Controls

Appropriate Engineering Controls : Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment : Gloves. Protective goggles.



Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection : In case of inadequate ventilation wear respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid
Appearance : Clear Yellow
Odor : Odorless
Odor Threshold : No data available
pH : 3.0 - 4.0
Evaporation Rate : No data available
Melting Point : No data available
Freezing Point : No data available
Boiling Point : 100 °C (212 °F)
Flash Point : Approximate to Water
Auto-ignition Temperature : No data available
Decomposition Temperature : No data available
Flammability (solid, gas) : No data available
Vapor Pressure : No data available
Relative Vapor Density at 20 °C : No data available
Relative Density : No data available
Specific Gravity : 1.016
Solubility : No data available
Partition Coefficient: N-Octanol/Water : No data available
Viscosity : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.
10.5. Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.
10.6. Hazardous Decomposition Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride gas. Ammonia. Hydrogen cyanide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

D-Glucitol (50-70-4)	
LD50 Oral Rat	15.9 g/kg
2-(Benzylmethylamino)ethyl methyl 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)pyridine-3,5-dicarboxylatemonohydrochloride (54527-84-3)	
LD50 Oral Rat	184 mg/kg
ATE (Dermal)	300.00 mg/kg body weight
ATE (Gases)	700.00 ppmV/4h

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ATE (Vapors)	3.00 mg/l/4h
ATE (Dust/Mist)	0.50 mg/l/4h

Skin Corrosion/Irritation: Not classified (pH: 3.0 - 4.0)
Serious Eye Damage/Irritation: Not classified (pH: 3.0 - 4.0)
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Carcinogenicity: Not classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Aspiration Hazard: Not classified
Symptoms/Injuries After Inhalation: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact: May cause skin irritation.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.
Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity**
Ecology - General : Not classified.
- 12.2. Persistence and Degradability** Not established
- 12.3. Bioaccumulative Potential** Not established
- 12.4. Mobility in Soil** No additional information available
- 12.5. Other Adverse Effects**
Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods**
Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.
Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.
Ecology – Waste Materials: Avoid release to the environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

- 14.1. In Accordance with DOT** Not regulated for transport
- 14.2. In Accordance with IMDG** Not regulated for transport
- 14.3. In Accordance with IATA** Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
D-Glucitol (50-70-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 01/14/2019
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Comb. Dust	Combustible Dust
H232	May form combustible dust concentrations in air
H301	Toxic if swallowed
H311	Toxic in contact with skin
H331	Toxic if inhaled

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Refer to American Regent prescribing information for further information at: <http://americanregent.com/AllProducts.aspx>

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