

Nicardipine Hydrochloride Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Nicardipine Hydrochloride Injection : 25 mg per 10 mL single dose vials, carton of 10
Other means of identification NDC 55150-183-10 (AuroMedics) NDC 55150-183-11 (Novaplus)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Irrit. 2 H315
Eye Irrit. 2 H319

Full text of hazard classes, H- and EUH-statements: see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



GHS07

Signal word (GHS US) :

Warning

Hazard statements (GHS US) :

H315 - Causes skin irritation
H319 - Causes serious eye irritation

Precautionary statements (GHS US) :

P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

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Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	> 94	Not classified
D-Glucitol	(CAS-No.) 50-70-4	4.8	Not classified
Sodium hydroxide	(CAS-No.) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Citric acid monohydrate	(CAS-No.) 5949-29-1	< 1	Eye Irrit. 2A, H319
Nicardipine Hydrochloride	(CAS-No.) 54527-84-3	0.25	Acute Tox. 3 (Oral), H301

Full text of hazard classes, H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

- Symptoms/injuries after inhalation : None anticipated during normal product use.
- Symptoms/injuries after skin contact : Causes skin irritation.
- Symptoms/injuries after eye contact : Causes serious eye irritation.
- Symptoms/injuries after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.
- Methods for cleaning up : Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

6.4. Reference to other sections

No additional information available

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m ³
OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
IDLH	IDLH	10 mg/m ³
NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
Citric acid monohydrate (5949-29-1)		
Not applicable		
Water (7732-18-5)		
Not applicable		
Nicardipine Hydrochloride (54527-84-3)		
Not applicable		
D-Glucitol (50-70-4)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : No protection is ordinarily required under normal conditions of use.
Eye protection : Wear safety glasses or goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : No protection is ordinarily required under normal conditions of use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : Yellow
Odor : Odorless
Odor threshold : No data available
pH : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : 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
Solubility : completely soluble.
Partition coefficient n-octanol/water (Log Pow) : No data available
Auto-ignition temperature : No data available

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Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg

Nicardipine Hydrochloride (54527-84-3)	
ATE US (oral)	100 mg/kg body weight

D-Glucitol (50-70-4)	
LD50 oral rat	15900 mg/kg

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Reproductive toxicity : Not classified
STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

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SECTION 12: Ecological information

12.1. Toxicity

Sodium hydroxide (1310-73-2)

LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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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

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A

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Skin Irrit. 2	Skin corrosion/irritation Category 2
H290	May be corrosive to metals
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.