

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 12/05/2024

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier Product Form: Mixture

Product Name: Nicardipine Hydrochloride Injection, USP

1.2. Intended Use of the Product

Use of the Substance/Mixture: Anti-hypertensive, treatment of chronic stable angina

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

Company

WG Critical Care, LLC

120 Route 17 North, Suite 115

Paramus, NJ 07652 USA

+ 1-888-493-0861

wgccquality@wgcriticalcare.com https://www.wgcriticalcare.com/

1.4. Emergency Telephone Number

Emergency Number: +1-866-562-4708 (ProPharma)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Acute toxicity (inhalation:dust,mist) Category 4

H332

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Warning

Hazard Statements (GHS-US)

: H332 - Harmful if inhaled.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.

P271 - Use only outdoors or in a well-ventilated area.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position

comfortable for breathing.

P312 - Call a poison center or doctor if you feel unwell.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

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	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA	(CAS-No.) 7732-18-5	98 – 99	Not classified.
Nicardipine hydrochloride	3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-, 3-methyl 5-[2-[methyl(phenylmethyl)amino]ethyl] ester, hydrochloride (1:1) nicardipine hydrochloride 2-(Benzylmethylamino)ethyl methyl 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)pyridine-3,5-dicarboxylatemonohydrochloride 3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(m-nitrophenyl)-, 2-(benzylmethyl amino)ethyl methyl ester, monohydrochloride 3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-, methyl 2-[methyl(phenylmethyl)amino]ethyl ester monohydrochloride	(CAS-No.) 54527-84-3	<1	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Inhalation:dust,mist), H330

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Sodium chloride	Sodium salt of hydrochloric acid Salt SEA SALT SODIUM CHLORIDE Sodium chloride (NaCl) Sea salt	(CAS-No.) 7647-14-5	< 1	Not classified.
D-Glucitol	Sorbitol D-Sorbitol Sorbitol, D- SORBITOL sorbitol	(CAS-No.) 50-70-4	< 1	Comb. Dust
Citric acid	1,2,3-Propanetricarboxylic acid, 2-hydroxy- CITRIC ACID 2-Hydroxypropane-1,2,3-tricarboxylic acid Anhydrous citric acid 2-Hydroxy-1,2,3-propanetricarboxylic acid Citric acid, anhydrous	(CAS-No.) 77-92-9	< 1	Eye Irrit. 2A, H319 STOT SE 3, H335 Comb. Dust
Sodium hydroxide	Caustic soda Sodium hydroxide (Na(OH)) SODIUM HYDROXIDE LYE	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

^{*} The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the 29 CFR 1910.1200. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). 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). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

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: Harmful if inhaled.

Symptoms/Injuries After Inhalation: Inhalation is likely to cause adverse health effects including but not limited to: irritation, difficulty breathing, and unconsciousness.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Chronic Symptoms: None expected under normal conditions of use.

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: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable. **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.

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Hazardous Combustion Products: Oxides of carbon, nitrogen, sodium, and chlorine compounds.

Other Information: No additional information available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions. Ventilate area.

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

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use. 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, spray. Use only outdoors or in a well-ventilated area. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

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. Store at controlled room temperature (20-25 °C / 68-77 °F). **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Anti-hypertensive, treatment of chronic stable angina

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), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Sodium hydr	oxide (1310-73-2)	
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
USA OSHA	OSHA PEL TWA	2 mg/m³

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when toxic gases may be released.

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Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.









Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection Skin and Body Protection

Chemical goggles or safety glasses.Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory

protection.

Thermal Hazard Protection

: Not applicable.

Environmental Exposure Controls Other Information

: Avoid unnecessary release into the environment.

: 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 yellowish liquidOdor: No data availableOdor Threshold: No data available

oH : 3.7 – 4.7

Evaporation Rate : No data available : No data available **Melting Point Freezing Point** : No data available **Boiling Point** > 100 °C (212 °F) **Flash Point** : No data available **Auto-ignition Temperature** : No data available **Decomposition Temperature** : No data available Flammability (solid, gas) : Not applicable **Vapor Pressure** No data available Relative Vapor Density at 20°C No data available : No data available **Relative Density** : 1.017 g/ml Density

Density : 1.017 g/ml
Solubility : Water: Miscible
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

Thermal decomposition may produce: Oxides of carbon, nitrogen, sodium, and chlorine compounds.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Inhalation:dust,mist: Harmful if inhaled.

Nicondining Hydrophlevide Injection LICD			
Nicardipine Hydrochloride Injection, USP			
ATE (Dust/Mist)	5.00 mg/l/4h		
Nicardipine hydrochloride (54527-84-3)			
LD50 Oral Rat	184 mg/kg (Source: NLM_CIP)		
ATE (Dust/Mist)	0.05 mg/l/4h		
Sodium chloride (7647-14-5)			
LD50 Oral Rat	3550 mg/kg (Species: Wistar)		
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)		
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h Source: ECHA_API)		
D-Glucitol (50-70-4)			
LD50 Oral Rat	15.9 g/kg		
Citric acid (77-92-9)			
LD50 Oral Rat	3 g/kg (Source: NLM_CIP)		
LD50 Dermal Rat	> 2000 mg/kg (Source: EU_CLH)		
Sodium hydroxide (1310-73-2)			
LD50 Oral Rat	325 mg/kg		
LD50 Dermal Rabbit	1350 mg/kg (Source: NLM_HSDB)		
Water (7732-18-5)			
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)		

Skin Corrosion/Irritation: Not classified.

pH: 3.7 - 4.7

Serious Eye Damage/Irritation: Not classified.

pH: 3.7 - 4.7

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: Inhalation is likely to cause adverse health effects including but not limited to: irritation,

difficulty breathing, and unconsciousness.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-
	through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)
Citric acid (77-92-9)	
LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus Source: OECD_SIDS)

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Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

12.2. Persistence and Degradability

Nicardipine Hydrochloride Injection, USP	
Persistence and Degradability Expected to be biodegradable.	
Citric acid (77-92-9)	
Persistence and Degradability	Readily biodegradable in water.

12.3. Bioaccumulative Potential

Nicardipine Hydrochloride Injection, USP		
Bioaccumulative Potential	Not expected to bioaccumulate.	
Sodium chloride (7647-14-5)		
BCF Fish 1	(no bioaccumulation)	
Citric acid (77-92-9)		
Partition coefficient n-octanol/water (Log	-1.72 (at 20 °C)	
Pow)		

12.4. Mobility in Soil

Nicardipine Hydrochloride Injection, USP	
Ecology - Soil	Adsorbs into the soil. Leaches if exposed to water.

12.5. Other Adverse Effects

Other Adverse Effects : None known.

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

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 unnecessary release into the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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

Nicardipine Hydrochloride Injection, USP			
SARA Section 311/312 Hazard Classes	Health hazard - Acute toxicity (any route of exposure)		
Sodium chloride (7647-14-5)			
Listed on the United States TSCA (Toxic Substances Contro	ol Act) inventory - Status: Active		
D-Glucitol (50-70-4)			
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active			
Citric acid (77-92-9)			
Listed on the United States TSCA (Toxic Substances Contro	ol Act) inventory - Status: Active		
Sodium hydroxide (1310-73-2)			
Listed on the United States TSCA (Toxic Substances Contro	ol Act) inventory - Status: Active		
CERCLA RO	1000 lb		

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Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. **US State Regulations**

Sodium hydroxide (1310-73-2)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

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

Date of Preparation or Latest Revision : 12/05/2024

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:

H290	May be corrosive to metals	
H301	Toxic if swallowed	
H302	Harmful if swallowed	
H312	Harmful in contact with skin	
H314	Causes severe skin burns and eye damage	
H318	Causes serious eye damage	
H319	Causes serious eye irritation	
H330	Fatal if inhaled	
H332	Harmful if inhaled	
H335	May cause respiratory irritation	
H402	Harmful to aquatic life	

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of

Health and Human Services) AU_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC_RAR: European Commission Renewal Assessment Report

EC SCOEL: European Commission Scientific Committee on Occupational

Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals

Reports

ECHA_API: European Chemicals Agency API

ECHA_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority EPA: U.S. Environmental Protection Agency

EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection

EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration

Eligibility Decision (U.S. Environmental Protection Agency)

EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection

Agency)

EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision

(U.S. Environmental Protection Agency)

EU CLH: European Union Harmonised Classification and Labelling Proposal

EU RAR: European Union Risk Assessment Report

FOOD_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately

Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN GHS: Japan GHS Basis for Classification Data

JP_J-CHECK: Japan J-Check

KR_NIER: South Korea National Institute of Environmental Research

Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment

Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S.

Department of Health and Human Services)

NLM_CIP: National Library of Medicine ChemID plus database

NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ_CCID: New Zealand Chemical Classification and Information Database OECD_EHSP: Environment, Health, and Safety Publication (Organisation for

Economic Co-operation and Development)

OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-

operation and Development) WHO: World Health Organization

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 quaranteeing any specific property of the product.

SDS US (GHS HazCom)

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