



MATERIAL SAFETY DATA SHEET

NICARDIPINE HYDROCHLORIDE INJECTION 25MG/10ML (2.5MG/ML)

1. IDENTIFICATION				
Material Identification	:	Nicardipine Hydrochloride Injection 25mg/10ml (2.5mg/ml)		
Active ingredient	:	1,4-Dihydro-2,6-dimethyl-4-(3-nitrophenyl)methyl-2-[methyl(Phenyl methyl)amino]-3,5-Pyridinedicarboxylic acid ethyl ester		
Molecular Formula	:	C ₂₆ H ₂₉ N ₃ O ₆ .HCL	Molecular Weight	: 479.5 g/mol
CAS Number	:	54527-84-3		
Product Use	:	Calcium Channel blocker		
Manufactured by	:	Micro Labs Limited Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra- Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	Manufactured for	: Armas Pharmaceuticals Inc., 303, W Main Street, Freehold, NJ 07728
Emergency Contact	:	+91-80-27839033		
2. HAZARDS IDENTIFICATION				
Label Elements				
Signal	:	None		
Physical hazards	:	Not classified		
Classification of the substance	:	Not classified		
Hazard statements	:	No known significant effects or critical hazards		
Precautionary statements	:	Not Applicable		
Supplementary Information	:	While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.		
Hazard(s) not otherwise classified (HNOC)	:	Not known.		
3. COMPOSITION/INFORMATION ON INGREDIENTS				
Chemical Name	CAS #	EINECS #	%w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Nicardipine Hydrochloride USP 1,4-Dihydro-2,6-dimethyl-4-(3-nitrophenyl)methyl-2-[methyl(Phenyl methyl)amino]-3,5-Pyridinedicarboxylic acid ethyl ester	54527-84-3	259-198-4	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Acute toxicity, Inhalation (Category 3) Hazard codes: H301, H351, H331, H311 Hazard symbol/Pictogram: GHS06



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Benzoic Acid Flakes USP	65-85-0	200-618-2	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Health hazard on Inhalation, Causes serious eye damage and skin irritation. Hazard codes: H315, H318, H372 Hazard symbol/Pictogram: GHS05, GHS08
Sodium Chloride USP (Injection grade)	7647-14-5	231-598-3	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Not Classified
Sodium Hydroxide USPNF (Injection grade)	1310-73-2	215-185-5	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Category 1/1A Hazard codes: H290, H314 Hazard symbol/Pictogram: GHS05

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eyes Contact	:	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. occasionally lifting the upper and lower eyelids. Get medical attention if irritation occurs
Skin Contact	:	Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.
Ingestion	:	Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

4. FIRST AID MEASURES

Inhalation	:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
Protection of First-Aiders:	:	No special protection is required.
Signs and Symptoms:	:	Not determined



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Medical Conditions Aggravated by Exposure:	:	No known significant effects or critical hazards
Notes to Physician:	:	Treat symptomatically
General information	:	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. Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.

5. FIRE FIGHTING MEASURES

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.
Specific hazards arising from the chemical	:	No specific fire or explosion hazard

General Information

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	For non-emergency personnel: Put on appropriate personal protective equipment. For emergency responders: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
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.



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7. HANDLING AND STORAGE

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
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Conditions for safe storage, including any incompatibilities

Storage conditions	:	Store at 200C TO 250C (680F TO 770F).
Specific end use(s)	:	The short term treatment of hypertension when oral therapy is not feasible or not desirable.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment	:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory Protection	:	In case of inadequate ventilation wear respiratory protection.
Hands	:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Eye Protection	:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts
Skin protection	:	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Liquid (Clear)
Color	:	Yellow
Appearance	:	Clear Yellow
Molecular Formula	:	C ₂₆ H ₂₉ N ₃ O ₆ .HCL
Molecular Weight	:	479.5 g/mol



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10. STABILITY AND REACTIVITY

Reactivity	:	Hazardous reactions will not occur under normal conditions.
Conditions to Avoid	:	Direct sunlight, extremely high or low temperatures, and incompatible materials.
Incompatible Materials	:	Strong acids. Strong bases. Strong oxidizers.
Hazardous Decomposition Products	:	Carbon oxides (CO, CO ₂). Nitrogen oxides. Hydrogen chloride gas. Ammonia. Hydrogen cyanide.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	:	Not classified			
		Chemical Name	Oral LD50	Dermal ATE	Gases ATE
		1,4-Dihydro-2,6-dimethyl-4-(3-nitrophenyl)methyl-2-[methyl(Phenyl methyl)amino]-3,5-Pyridinedicarboxylic acid ethyl ester	184 mg/kg	300.00 mg/kg body weight	700.00 ppmV/4h
Skin Irritation/Sensitization	:	No known significant effects or critical hazards.			
Eye irritation	:	No known significant effects or critical hazards.			
Germ cell mutagenicity	:	No known significant effects or critical hazards.			
Carcinogenicity	:	No known significant effects or critical hazards.			
IARC:	:	No known significant effects or critical hazards.			
NTP:	:	No known significant effects or critical hazards.			
OSHA:	:	No known significant effects or critical hazards.			
Reproductive toxicity:	:	Not Classified			

12. ECOLOGICAL INFORMATION

Toxicity:	:	Not classified
Persistence and degradability	:	No data available
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available



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Results of PBT and vPvB	:	No data available
13. DISPOSAL CONSIDERATIONS		
Waste Treatment Methods	:	The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
14. TRANSPORTATION INFORMATION		
Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	Not applicable
Packing group	:	Not applicable
IATA UN number	:	Not applicable
There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.		
15. REGULATORY / STATUTORY INFORMATION		
Seveso regulation (Directive 96/82/EC)	:	Not Available
Candidate list (art. 59-REACH):	:	Not Available
Ozone depletion substance (2000/2037/EC)	:	Not Available
Import/export dangerous chemical (2008/689/EC)	:	Not Available



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16. OTHER INFORMATION

Date of preparation: 06/03/24

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet