SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	**NIFEDIPINE, USP**
PRODUCT CODE	**0280**
SUPPLIER	**MEDISCA Inc.** Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 **MEDISCA Pharmaceutique Inc.** Tel.: 1.800.665.6334 | Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 **MEDISCA Australia PTY LTD** Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Toxic to Reproduction (Category 2) Acute Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	Harmful if swallowed. May cause an allergic reaction. Suspected of damaging fertility or the unborn child. Toxic to aquatic life.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)	**Prevention**	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection.
	Response	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice.
	Storage	Store locked up.
	Disposal	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION	**Health Hazard**	2	**Flammability**	0
	Reactivity	0	**Personal Protection**	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-, dimethyl ester
BOTANICAL NAME	Not applicable
SYNONYM	Not applicable
CHEMICAL FORMULA	$C_{17}H_{18}N_2O_6$
CHEMICAL FAMILY	Dihydropyridine
CAS NUMBER	21829-25-4
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	346.3372

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
NIFEDIPINE	21829-25-4	244-598-3	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	**Small fire:** dry chemical, CO_2 or water spray. **Large fire:** dry chemical, CO_2, alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.
CLEANUP PROCEDURE	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.
REFERENCE TO OTHER SECTIONS	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING	Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
CONDITIONS FOR SAFE STORAGE	Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
STORAGE CONDITIONS	Store in original container, tightly sealed, protected from direct sunlight and moisture. Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: NIFEDIPINE CAS #: 21829-25-4

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available
PELs are 8-hour TWAs = Limit value - Eight hours
Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

PERSONAL PROTECTIVE EQUIPMENT
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING
Not available

CONTROL BANDING
Not available

NOTES
OEL advisable as per MFG: 0.3 mg/m³
USP: ELV: Industrial: TWA: 300 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
Yellow powder. Is affected by exposure to light.

SOLUBILITY
Practically insoluble in water; freely soluble in acetone.

ODOR
Characteristic odor or essentially odorless.

FLAMMABILITY
May be combustible at high temperature

AUTO-IGNITION TEMPERATURE	Not available	**BOILING POINT**	Not available	**DECOMPOSITION TEMPERATURE**	Not available
EVAPORATION RATE	Not available	**EXPLOSIVE LIMIT**	Not available	**FLASH POINT**	Not available

log P (OCTANOL-WATER)	2.2 (20°C)	**LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	Not available	**MELTING/FREEZING POINT**	(171 - 177)°C, (339.8 - 350.6)°F
PARTICLE CHARACTERISTICS	Not available	**OXIDIZING PROPERTY**	Not available	**pH**	Not available
RELATIVE DENSITY (WATER = 1)	Not available	**SPECIFIC GRAVITY**	Not available	**UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	Not available
VAPOR DENSITY (AIR = 1)	Not available	**VAPOR PRESSURE**	< 0.0000001 kPa (25 °C)	**VISCOSITY**	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants, strong bases and strong acids.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBLITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures. Light sensitive.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 1022 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Based on available data, the classification criteria are not met. Nifedipine is associated with various hypersensitivity reactions including skin rashes and effects on the liver.

GERM CELL MUTAGENICITY	Based on available data, the classification criteria are not met. Mutagenicity: Ames test in S. typhimurium, with and without activation: Negative. In vivo Cytogenetics assay: Hamster: Negative. In vivo dominant lethal assay: Mice: Negative. In vivo micronucleus test: Mice: Negative. Suspected mutagen: KNN Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability)	
CARCINOGENICITY	**OSHA**	NIFEDIPINE is not listed.
	NTP	NIFEDIPINE is not listed.
	IARC	NIFEDIPINE is not evaluated.
	California Proposition	This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: NIFEDIPINE.
ADDITIONAL CARCINOGENICITY INFORMATION	Based on available data, the classification criteria are not met.	
REPRODUCTIVE TOXICITY	Nifedipine is reported to be teratogenic in animals and may inhibit labour, but it has been used in hypertension in pregnancy. In animals, many of the processes of embryogenesis appear to be calcium-dependent, and there are theoretical concerns about use of calcium channel blockers by humans in early pregnancy. However, epidemiological studies have not shown an association between therapeutic use of calcium channel blocking agents during pregnancy and an increased incidence of birth defects. Nifedipine is distributed into breast milk but the amount present is probably too small to be harmful. There have been no reports of any clinical effects in breast-fed infants whose mothers were receiving nifedipine and the American Academy of Pediatrics therefore considers that it is usually compatible with breast feeding. Reproductivity and development study: Rabbit: 3.5 to 14 times the human dose: Digital abnormalities. Reproductivity and development study: Rat: 9 to 62 times the human dose: Fetotoxicity and increased incidence of skeletal and cardiovascular malformations. Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability)	
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Based on available data, the classification criteria are not met.	
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Based on available data, the classification criteria are not met.	
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.	

SIGNS AND SYMPTOMS OF EXPOSURE		ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Calcium channel blocking agents: Low blood pressure. Pulmonary edema. Cardiac dysrhythmias. Hyperglycemia. Circulatory problems. Metabolic acidosis. Cross sensitivity: Persons sensitive to other calcium channel blockers may be sensitive to this material also. Symptoms related to the physical, chemical, and toxicological characteristics: Chest pain. Frequent, painful, or difficult urination. Eye pain. Nervousness. Calcium channel blocking agents: Dizziness. Headache. Sleep disturbances. Weakness. Flushing. Nausea. Heartburn. Constipation. Skin rash. Muscle cramps. Swelling of legs. Fast or pounding heartbeat. Slow heartbeat. Swollen or bleeding gums. Coughing. Difficulty breathing. Medical conditions aggravated by exposure: Angina. Aortic stenosis. Calcium channel blocking agents: Heart failure. Kidney disease. Liver disease. Blood vessel disorders. Gastroesophageal reflux. Hypotension. Peripheral edema. Diabetes. Cross sensitivity: Persons sensitive to other calcium channel blockers may be sensitive to this material also.
POTENTIAL HEALTH EFFECTS	**Inhalation**	May be harmful if inhaled. May cause respiratory tract irritation.
	Ingestion	Harmful if swallowed.
	Skin	May be harmful if absorbed through skin. Causes skin irritation. May cause allergic reaction.
	Eyes	May cause serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): > 3.88 LC50: 96 Hr: Fish: (mg/L): > 5.77 EC50: 96 Hr: Green Algae: (mg/L): 2.91*
PERSISTENCE AND DEGRADABILITY	Not readily biodegradable. # Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is Possible NON Readily Biodegradable (moderate reliability)
BIOACCUMULATIVE POTENTIAL	Log Pow: 2.2 (20°C)
MOBILITY IN SOIL	Practically insoluble in water. Water Solubility: 56.3 mg/L (25°C) Henry's Law Constant: 7.31E-14 atm-m³/mole (25°C)
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment
NOTES	*Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

HAZCHEM	Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusett	California Prop 65
NIFEDIPINE 21829-25-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
NIFEDIPINE 21829-25-4	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
NIFEDIPINE 21829-25-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT	Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES	Available upon request
ABBREVIATIONS AND ACRONYMS	**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Instituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System
LAST REVISION	03/2023
SUPERSEDES	05/2021
	For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com
DISCLAIMER	This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.
SUPPLEMENTARY INFORMATION	For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.