SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: NIFEDIPINE, USP
PRODUCT CODE: 0280
SUPPLIER: MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
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

USES
Antianginal; vasodilator.

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.

AUSTRALIA-ONLY HAZARDS
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 special instructions before use.
Do not handle until all safety precautions have been read and understood.
Protective gloves, protective clothing, eye protection, face protection.

Response
IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
IF EXPOSED OR CONCERNED: Get medical advice/attention.

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_{2}O_{6} |
| CAS NUMBER | 21829-25-4 |
| ALTERNATE CAS NUMBER | Not applicable |
| MOLECULAR WEIGHT | 346.3372 |

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 | 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. |
| EXTINGUISHING MEDIA | Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, 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.

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.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Recommended storage temperature: Room temperature. Preserve in tight, light-resistant containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

<table>
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<tr>
<th>OSHA PEL</th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
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</table>

N/L = Not Listed

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.

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

NOTES
OEL advisable as per MFG: 0.3 mg/m3
USP 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

<table>
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<th>Property</th>
<th>Value</th>
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<td>May be combustible at high temperature</td>
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</tbody>
</table>

### ODOR THRESHOLD

- Not available

### pH

- Not available

### MELTING POINT

- (171 - 177)°C, (339.8 - 350.6)°F

### BOILING POINT

- Not available

### FREEZING POINT

- (171 - 177)°C, (339.8 - 350.6)°F

### FLASH POINT

- Not available

### SPECIFIC GRAVITY

- Not available

### EVAPORATION RATE

- Not available

### EXPLOSIVE LIMIT

- Not available

### UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

- Not available

### LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

- Not available

### VAPOR DENSITY (AIR = 1)

- Not available

### RELATIVE DENSITY (WATER = 1)

- Not available

### DECOMPOSITION TEMPERATURE

- Not available

### VAPOR PRESSURE

- < 0.0000001 kPa (25 °C)

### LOG P (OCTANOL-WATER)

- 2.2 (20°C)

### SECTION 10: STABILITY AND REACTIVITY

- **Reactivity:** Not established
- **Stability:** Stable under recommended storage conditions
- **Materials to Avoid:** 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
- **Possibility 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: LD50: (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 or Skin Sensitization:**
  - Nifedipine is associated with various hypersensitivity reactions including skin rashes and effects on the liver. Cross sensitivity: Persons sensitive to other calcium channel blockers may be sensitive to this material also.
GERM CELL MUTAGENICITY

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.

Based on available data, the classification criteria are not met.

CARCINOGENICITY

OSHA  NIFEDIPINE is not listed.
NTP  NIFEDIPINE is not listed.
IARC  NIFEDIPINE is not evaluated.
California  Proposition 65  This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: NIFEDIPINE.

ADDITIONAL CARCINOGENICITY INFORMATION

Long-term carcinogenicity study: Rat: 2 years: 156 - 210 mg/kg/day: administered orally: Not carcinogenic.

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.

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

Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics: Chest pain. Frequent, painful, or delayed or immediate effects of 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.


SIGNS AND SYMPTOMS OF EXPOSURE

Inhalation  Harmful if inhaled. May cause respiratory tract irritation.

Ingestion  Harmful if swallowed.

Skin  May be harmful if absorbed through skin. Causes skin irritation.

Eyes  Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Daphnia magna: (mg/L): > 3.88
LC50: 96 Hr: Fish: (mg/L): > 5.77
IC50: 72 Hr: Algae: (mg/L): Not available
SAFETY DATA SHEET

PERSISTENCE AND DEGRADABILITY
Not readily biodegradable.

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

SECTION 13: DISPOSAL CONSIDERATIONS

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

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME
Not dangerous good
UN NUMBER
Not applicable
CLASS
Not applicable
PACKING GROUP
Not applicable

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

ENVIRONMENTAL HAZARDS
Not available

SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
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<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
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N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
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<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION
02/2016

SUPERSEDES
09/2013

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.