

## SAFETY DATA SHEET

Preparation Date: 7/16/2015

Revision Date: 6/13/2018

Revision Number: G2

### 1. IDENTIFICATION

**Product identifier**

**Product code:** NI113  
**Product Name:** NIFEDIPINE, MICRONIZED, USP

**Other means of identification**

**Synonyms:** 3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-, dimethyl ester  
 Adalat/Adalate  
 Citilat  
 Corinfar  
 Fenihidin/Fenihidine  
 Oxcord  
 procardia  
 1,4-Dihydro-2,6-dimethyl-4-(2-nitrophenyl)-3,5-pyridinedicarboxylic acid dimethyl ester  
 Dimethyl 1,4-dihydro-2,6-dimethyl-4-(2'-nitrophenyl)-3,5-pyridinedicarboxylate  
 4-(2'Nitrophenyl)-2,6-dimethyl-3,5-diacarbomethoxy-1,4-dihydropyridine

**CAS #:** 21829-25-4  
**RTECS #** US7975000  
**CI#:** Not available

**Recommended use of the chemical and restrictions on use**

**Recommended use:** Drug.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
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**Label elements**

**Warning****Hazard statements**  
Harmful if swallowed**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this productIF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Nifedipine	21829-25-4	100

**4. FIRST AID MEASURES****First aid measures**

- General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
- Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
- Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
- Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
- Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

**Most important symptoms and effects, both acute and delayed**

- Symptoms**
- May cause eye irritation
  - May cause skin irritation
  - May cause respiratory irritation

It may affect the blood  
May affect the cardiovascular system  
May affect behavior/central nervous system

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Oxides. Nitrogen Oxides.

**Specific hazards:** May be combustible at high temperatures. Fire may produce irritating and/or toxic gases.

**Special Protective Actions for Firefighters**

**Specific Methods:** No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Remove all sources of ignition. All equipment used when handling the product must be grounded.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

**Methods and material for containment and cleaning up**

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE**

**Precautions for safe handling**

**Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. All equipment used when handling the product must be grounded. Remove all sources of ignition. Keep away from incompatible materials.

**Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities****Technical Measures/Storage Conditions:**

Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition. Store away from incompatible materials.

**Incompatible Materials:**

Oxidizing agents

<b>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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**Control parameters****National occupational exposure limits****United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Nifedipine	21829-25-4	None	None	None	None

**Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Nifedipine	21829-25-4	None	None	None	None

**Australia and Mexico**

Components	CAS-No.	Australia	Mexico
Nifedipine	21829-25-4	None	None

**Appropriate engineering controls****Engineering measures to reduce exposure:**

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Individual protection measures, such as personal protective equipment****Personal Protective Equipment**

**Eye protection:** Safety glasses with side-shields

**Skin and body protection:** Chemical resistant apron  
Long sleeved clothing

Gloves

**Respiratory protection:** Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Powder.	<b>Color:</b> Yellow.
<b>Odor:</b> No information available.	<b>Taste</b> No information available.	<b>Formula:</b> C17H18N2O6
<b>Molecular/Formula weight:</b> 346.33g/mol	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 171-177°C/340-351°F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> 2.2	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Insoluble in cold water Insoluble in hot water Soluble in Ethanol Soluble in Dimethyl Sulfoxide Soluble in Chloroform Soluble in Acetone	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with strong oxidizing agents

### Chemical stability

**Stability:** Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

**Product code:** NI113

**Product name:** NIFEDIPINE,  
MICRONIZED, USP

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**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Avoid dust formation. Incompatible materials. Exposure to light.

**Incompatible Materials:** Oxidizing agents

**Hazardous decomposition products:** Nitrogen oxides (NOx). Carbon oxides.

**Other Information**

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation. Eyes. Skin.

### Acute Toxicity

#### Component Information

Nifedipine	
CAS-No.	21829-25-4

**LD50/oral/rat** = 1022 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = 494mg/kg oral LD50 mouse  
310mg/kg oral LD50 mouse  
202mg/kg oral LD50 mouse  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50information** = 504mg/kg oral LD50 rabbit  
100mg/kg oral LD50 cat

#### Product Information

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 1022 mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = 202 mg/kg

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal** = No information available

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

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**LC50/Inhalation/mouse**

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

**Symptoms****Skin Contact:** May cause skin irritation.**Eye Contact:** May cause eye irritation.**Inhalation** May cause respiratory tract irritation.

**Ingestion** Harmful if swallowed. May cause upset stomach, vomiting, nausea, heartburn, constipation, difficulty swallowing, muscle cramps, . May affect behavior/central nervous system (somnolence, dizziness, lightheadedness, giddiness, fainting, headache, tremor, nervousness, mood changes, sleep disturbances, blurred vision, convulsions, ataxia, depression, paranoid syndrome), cardiovascular system (hypotension, palpitations, fast heartbeat, regional or general arteriolar or venous dilation, peripheral edema, myocardial infarction, ventricular arrhythmias or conduction disturbances, congestive heart failure), liver (elevated liver enzymes, jaundice, cholestasis with or without jaundice), respiration (dyspnea, respiratory stimulation, coughing, wheezing, pulmonary edema), blood (decreases platelet aggregation and an increase in bleeding time, anemia, leulopenia, purpura), urinary system (nocturia, polyuria). May also cause nasal and chest congestion, sore throat, flushing, heat sensation, cough, wheezing, angioedema, (mostly oropharyngeal edema with breathing difficulty and shortness of breath), gingival hyperplasia or enlargement of gum tissue around teeth, excessive tiredness, weakness, decreased sexual ability.

**Aspiration hazard** No information available.**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Chronic Toxicity** No information available.**Sensitization:** No information available.**Mutagenic Effects:** No information available**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Nifedipine	21829-25-4	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)**IARC (International Agency for Research on Cancer)**NTP (National Toxicology Program)**OSHA (Occupational Safety and Health Administration of the US Department of Labor)***Reproductive toxicity** No data is available**Reproductive Effects:** May cause adverse reproductive effects based on animal data

**Developmental Effects:** There are no adequate and well-controlled studies in humans. Data in humans were insufficient to evaluate the effects on reproduction  
 May cause adverse developmental effects based on animal data

**Teratogenic Effects:** There are no adequate and well-controlled studies in humans  
 May cause birth defects (teratogenic effects) based on animal test data  
 There are no adequate and well-controlled studies in humans

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** Blood. Central nervous system. Cardiovascular system.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility:** No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Waste from residues / unused products:**  
 Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**  
 Dispose of as unused product. Dispose of in accordance with federal, state and local regulations Do not re-use empty containers Empty containers should be taken for local recycling, recovery or waste disposal.

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Nifedipine	21829-25-4	None	None	None	None

**14. TRANSPORT INFORMATION**

**DOT**

**UN-No:** Not Regulated

**Proper Shipping Name:** No information available

**Hazard Class:** No information available

**Subsidiary Class** No information available

**Packing group:** No information available

**Emergency Response Guide Number** No information available

**Marine Pollutant** No data available

**DOT RQ (lbs):** No information available

**Special Provisions** No Information available

**Symbol(s):** No information available

**Description:** No information available



**TDG (Canada)**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant Description:** No Information available  
 No information available

**ADR**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

**IMO / IMDG**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

**RID**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**ICAO**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Nifedipine</i>	21829-25-4	Not Listed	Present KE-10622	Not present	Not present	Not present	Present	Present 244-598-3

**U.S. Regulations**

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Nifedipine	21829-25-4	Not Listed	developmental toxicity	male reproductive toxicity	female reproductive toxicity

**CERCLA/SARA**

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Nifedipine	21829-25-4	None	None	None	None	None

**U.S. TSCA**

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Nifedipine	21829-25-4	Not Applicable	Not Applicable

**Canada****WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information: The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

**WHMIS 1988 Hazard Class**

The classification of this product has not been validated yet

**Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

**Inventory**

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Nifedipine	21829-25-4	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Nifedipine	21829-25-4	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Nifedipine	21829-25-4	Not listed

## EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Nifedipine	21829-25-4	No information

EU - CLP (1272/2008)

### R-phrase(s)

R22 - Harmful if swallowed.

### S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Nifedipine	21829-25-4		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

### Indication of danger:

Xn - Harmful.

Xn



## 16. OTHER INFORMATION

**Preparation Date:** 7/16/2015  
**Revision Date:** 6/13/2018  
**Prepared by:** Sonia Owen

### Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet