

SAFETY DATA SHEETS

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - Sixth revised edition

Version: 1.0

Creation Date: Aug 11, 2017

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1. Identification

1.1 GHS Product identifier

Product name nifedipine

1.2 Other means of identification

Product number -

Other names dimethyl 2,6-dimethyl-4-(2-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate

1.3 Recommended use of the chemical and restrictions on use

Identified uses For industry use only.

Uses advised against no data available

2. Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Oral, Category 4

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Warning

Hazard statement(s)

H302 Harmful if swallowed

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/...if you feel unwell.

P330 Rinse mouth.

Storage

none

Disposal

P501 Dispose of contents/container to ...

2.3 Other hazards which do not result in classification

none

3. Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
nifedipine	nifedipine	21829-25-4	none	100%

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound via ingestion include diabetes mellitus, hallucinations, distorted perceptions, cardiac effects, nausea, vomiting, changes in regional blood flow, dermatitis, anaphylaxis and decreased blood pressure. Other symptoms via ingestion include headache, dizziness, flushing, hypotension, tachycardia, fatigue and edema. It also causes dilation of coronary arteries and arterioles, reduced oxygen requirements, decreased platelet aggregation, weakness, heartburn, muscle cramps, tremor, nervousness, mood changes, palpitation, dyspnea, wheezing, cough, nasal congestion, sore throat, chest congestion, diarrhea, constipation flatulence, muscle inflammation, joint stiffness, shakiness, blurred vision, difficulties in balance, jitteriness, sleep disturbances, pruritus, urticaria, fever, sweating, chills, sexual difficulties and syncopal episodes. It can cause bradycardia, lethargy and anginal pain. It can also cause improved contractility and segmental ventricular function, increased heart rate and cardiac output, and increased peripheral blood flow due to arterial dilation (with no change in venous tone). It can cause negative inotropy, excessive vasodilation, depression of the sinus nodal rate, A-V nodal conduction disturbances, digital dysesthesia, sedation and aggravation of myocardial ischemia. Somnolence may occur.

ACUTE/CHRONIC HAZARDS: When heated to decomposition this compound emits toxic fumes of nitrogen oxides.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Generally, overdosage with nifedipine leading to pronounced hypotension calls for active cardiovascular support including monitoring of cardiovascular and respiratory function, elevation of extremities, judicious use of calcium infusion, pressor agents and fluids. Clearance of nifedipine would be expected to be prolonged in patients with impaired liver function. Since nifedipine is highly protein bound, dialysis is not likely to be of any benefit; however, plasmapheresis may be beneficial.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. A water spray may also be used.

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably combustible.

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Nifedipine liquid-filled capsules should be protected from light and moisture

and stored in tight, light-resistant containers at a temperature of 15-25°C, and extended-release tablets of the drug should be protected from light and moisture and stored in tight, light-resistant containers at a temperature less than 30°C.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

Wear dust mask when handling large quantities.

Thermal hazards

no data available

9. Physical and chemical properties

Physical state	Yellow Crystalline Solid
Colour	Yellow crystals
Odour	no data available
Melting point/ freezing point	-77°C(lit.)
Boiling point or initial boiling point and boiling range	173°C(lit.)
Flammability	no data available
Lower and upper explosion limit / flammability limit	no data available
Flash point	53°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 19.5°C
Partition coefficient n-octanol/water (log value)	no data available
Vapour pressure	2.68E-08mmHg at 25°C
Density and/or relative density	1.271g/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

10. Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

NIFEDIPINE is sensitive to light.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

When heated to decomposition, it emits toxic fumes of /nitrogen oxides/.

11. Toxicological information

Acute toxicity

- Oral: LD50 Rat oral 1022 mg/kg
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

An estimated BCF of 13 was calculated for Nifedipine(SRC), using a log Kow of 2.20(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

12.4 Mobility in soil

The Koc of Nifedipine is estimated as 370(SRC), using a log Kow of 2.20(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that Nifedipine is expected to have moderate mobility in soil.

12.5 Other adverse effects

no data available

13. Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. Transport information

14.1 UN Number

ADR/RID: Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

14.2 UN Proper Shipping Name

ADR/RID: unknown

IMDG: unknown

IATA: unknown

14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

14.4 Packing group, if applicable

ADR/RID: Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

14.5 Environmental hazards

ADR/RID: no

IMDG: no

IATA: no

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

15. Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
nifedipine	nifedipine	21829-25-4	none
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Not Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.

16. Other information

Information on revision

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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods

- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website:
<http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website:
<https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website:
<http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website:
http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website:
<http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website:
<http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website:
<http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Disclaimer: 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. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.