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PRODUCT AND COMPANY IDENTIFICATION

GHS Product Name: Nifedipine
Product code: h-314
Company: PharmSintez.Lab
Address: Skolkovo Nobel street, 5, Lab. 3a, 09. 556. Moscow, Russia
Tel: +7 (495) 796-94-33
Fax: +7 (495) 796-94-33
Email: info@labphs.com

1.1 Product identifiers

| | |
|---------------------------|-----------------|
| Product name: | Nifedipine |
| Product Catalogue Number: | h-314 |
| Band: | PharmSintez.Lab |
| CAS-No: | 21829-25-4 |

1.2 Relevant identified uses of the substance or mixture and uses advised against

| | |
|------------------|---|
| Identified uses: | For research use only. Not intended for diagnostic or therapeutic use |
|------------------|---|

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral

Category 4 - (H302)

Classification according to 67/548/EEC

Hazard symbols

T - Toxic

R-code(s)

Repr. cat. 2;R60 - Repr. cat. 2;R61 - Xn;R22 - R43

2.2. Label Elements

Contains Nifedipine

Signal word

Warning

Symbols/Pictograms



Hazard statements

H302 - Harmful if swallowed

EUH210 - Safety data sheet available on request

2.3. Other Hazards

General Hazards

Not applicable

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Molecular Weight 346.33
Formula $C_{17}H_{18}N_2O_6$

3.1 Substances

| Chemical Name | EC No | CAS No | Weight % | Classification according to 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---------------|---------|------------|----------|---|---|
| Nifedipine | Present | 21829-25-4 | 100 | Xn;R 22 Xi;R4 3 Repr.Cat.2;R6 0-61 | Acute Tox. 4 (H302) |

Full text of R-phrases: see section 16

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

| | |
|--|--|
| General advice | Immediate medical attention is required. |
| Inhalation | Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Immediate medical attention is required. If not breathing, give artificial respiration. |
| Skin Contact | Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Wash off immediately with soap and plenty of water. |
| Eye contact | Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately. |
| Ingestion | Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Call a physician or poison control center immediately. |
| Self-protection of the first aider clothing. | Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. |

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization of susceptible persons.

Section 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

In the event of fire and/or explosion do not breathe fumes May cause sensitization by inhalation and skin contact

Thermal decomposition can lead to release of irritating and toxic gases and vapors

Hazardous combustion products Carbon oxides. Nitrogen oxides (NOx).

5.3. Advice for firefighters Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment as required. Keep people away from and upwind of

spill/leak.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or

tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp

to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly. Soak up with inert absorbent material.

6.4. Reference to other sections

See Section 12: ECOLOGICAL INFORMATION.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Wash contaminated clothing before reuse. Do not

eat, drink or smoke when using this product. Use personal protective equipment as required. Do not breathe dust/fume/gas/mist/vapors/spray.

General Hygiene Considerations and When using do not eat, drink or smoke. Regular cleaning of equipment, work area

clothing is recommended. Avoid contact with skin, eyes or clothing. Wash hands thoroughly after handling. Keep away from food, drink and animal feeding stuffs.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of

children. Keep containers tightly closed in a cool, well-ventilated place.

7.3. Specific end use(s)

Pharm Sintez.Lab Cat# h-314

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

| | |
|--|--|
| Exposure Limits occupational | This product, as supplied, does not contain any hazardous materials with exposure limits established by the region specific regulatory bodies. |
| Derived No Effect Level (DNEL) | No information available |
| Predicted No Effect Concentration (PNEC) | No information available. |

8.2. Exposure controls

| | |
|---------------------------------|--|
| Engineering Controls | Showers Eyewash stations Ventilation systems |
| Eye/face protection | Tight sealing safety goggles. |
| Skin and Body Protection | Suitable protective clothing. Gloves made of plastic or rubber. |
| Respiratory protection approved | If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations. |
| Environmental exposure controls | No information available. |

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

| | |
|----------------|--------------------------|
| Physical State | Solid |
| Appearance | No information available |
| Odor | No information available |

Property
pH

Values
No information available

| | |
|------------------------------|--------------------------|
| Melting point/freezing point | 173 °C |
| Boiling point | No information available |
| Flash point | No information available |
| Density | No information available |
| Evaporation rate | No information available |
| Upper flammability limits | No information available |
| Lower flammability limit | No information available |
| Vapor pressure | No information available |
| Vapor density | No information available |
| Specific gravity | No information available |
| Water solubility | No information available |
| Solubility in other solvents | No information available |
| Partition coefficient | No information available |
| Autoignition temperature | No information available |
| Decomposition temperature | No information available |
| Kinematic viscosity | No information available |
| Explosive properties | No information available |
| Oxidizing properties | No information available |

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity Not applicable

10.2. Chemical stability

Stability Stable under recommended storage conditions. Sensitivity to Mechanical Impact No information available.
Sensitivity to Static Discharge No information available.

10.3. Possibility of hazardous reactions

Hazardous polymerization No information available.
Possibility of Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Extremes of temperature and direct sunlight.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous Decomposition Products Carbon oxides. Nitrogen oxides (NO_x).

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Product Information Product does not present an acute toxicity hazard based on known or supplied information.

Unknown acute toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 1,022.00 mg/kg

| Chemical | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|------------|----------------|-------------|-----------------|
| Nifedipine | = 1022 mg/kg (| | |

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity May cause long lasting harmful effects to aquatic life.
 Unknown aquatic toxicity 100% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products Disposal should be in accordance with applicable regional, national and local laws and

regulations.
 Contaminated packaging Do not reuse container.
 Other Information Waste codes should be assigned by the user based on the application for which the product was used.

Section 14: TRANSPORT INFORMATION

| | <u>RID / ADR</u> Not regulated | <u>IMDG</u> Not | <u>ICAO (air) / IATA</u> Not regulated |
|----------------------------------|-----------------------------------|--------------------|---|
| 14.1 UN/ID no | - | - | - |
| 14.2 Proper shipping name | - | - | - |
| 14.3 Hazard Class | - | - | - |
| Subsidiary hazard class / Labels | - | - | - |
| 14.4 Packing Group | - | - | - |
| 14.5 Environmental Hazard | - | - | - |
| Special Provisions | - | - | - |

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National Regulations**European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

International Inventories

All of the components in the product are on the following Inventory lists

Canada (DSL/NDSL) Europe (EINECS/ELINCS/NLP) Australia (AICS) South Korea (KECL):

| Chemical | TSCA | DSL | NDSL | EINEC | ELINC | ENCS | IECSC | KECL | PICCS | AIC |
|------------|------|-----|------|-------|-------|------|-------|------|-------|-----|
| Nifedipine | - | X | - | X | - | - | - | X | - | X |

X - Listed

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical

Substances **IECSC** - China Inventory of Existing

Chemical Substances **KECL** - Korean Existing

and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

No information available

Section 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3

R61 - May cause harm to the unborn

child R60 - May impair fertility

R43 - May cause sensitization by skin

contact R22 - Also harmful if swallowed

Full text of H-Statements referred to under sections 2 and 3
swallowed Revision note

H302 - Harmful if

No information available.

Further information

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See www.labphs.com for additional terms and conditions of sale.

Preparation Information

PharmSintez.Lab

Product Safety – multiple

Region Tel: +7 (495) 796-

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