# SAFETY DATA SHEET



Revision Date 08-Nov-2010

**Revision Number** 2

# **1. PRODUCT AND COMPANY IDENTIFICATION**

| Product Identifier   |
|----------------------|
| Product Description: |
| Cat No.              |
| Synonyms             |

Nifedipine 329270000; 329270050 Adalate; Procardia; Corinfar.

Relevant identified uses of the substance or mixture and uses advised againstRecommended UseLaboratory chemicalsUses advised againstNo Information available

 Details of the supplier of the safety data sheet

 Company

 Acros Organics BVBA

 Janssen Pharmaceuticalaan 3a

 2440 Geel, Belgium

 E-mail address
 begel.sdsdesk@thermofisher.com

 Emergency Telephone Number

 For information in the US, call: 800-ACROS-01

 For information in Europe, call: +32 14 57 52 11

Emergency Number, Europe: +32 14 57 52 99 Emergency Number, US: 201-796-7100

CHEMTREC Phone Number, US: 800-424-9300 CHEMTREC Phone Number, Europe: 703-527-3887

# 2. HAZARDS IDENTIFICATION

Classification of the substance or mixture REGULATION (EC) No 1272/2008

Acute oral toxicity

Category 4

Classification according to EU Directives 67/548/EEC or 1999/45/ECFor the full text of the R phrases mentioned in this Section, see Section 16Symbol(s)Xn - HarmfulR -phrase(s)R22 - Harmful if swallowed

Label Elements



Signal Word

Warning

### Hazard Statements

H302 - Harmful if swallowed

#### Precautionary Statements - EU (§28, 1272/2008)

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

#### Other Hazards

No information available.

# **3. COMPOSITION/INFORMATION ON INGREDIENTS**

| Component                | EC No.       | Weight % | CAS-No     | Classification | GHSCLAS             |
|--------------------------|--------------|----------|------------|----------------|---------------------|
| 3,5-Pyridinedicarboxylic | EEC No. 244- | 100      | 21829-25-4 | Xn; R22        | Acute Tox. 4 (H302) |
| acid, 1,4-dihydro-2,6-   | 598-3        |          |            |                |                     |
| dimethyl-4-(2-           |              |          |            |                |                     |
| nitrophenyl)-, dimethyl  |              |          |            |                |                     |
| ester                    |              |          |            |                |                     |

### For the full text of the R phrases mentioned in this Section, see Section 16

# 4. FIRST AID MEASURES

| Description of first aid measures<br>Eye Contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes Obtain medical attention   |
|--|--|
| Skin Contact                                     | Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes Obtain medical attention  |
| Ingestion  | Clean mouth with water Get medical attention   |
| Inhalation                                       | Remove from exposure, lie down Move to fresh air If breathing is difficult, give oxygen If not breathing, give artificial respiration Obtain medical attention |
| Notes to Physician                               | Treat symptomatically  |

# **5. FIRE-FIGHTING MEASURES**

Extinguishing media Suitable Extinguishing Media Water spray Carbon dioxide (CO<sub>2</sub>) Dry chemical chemical foam

#### **Extinguishing media which must not be used for safety reasons** No information available.

#### Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors

#### Advice for fire-fighters

#### ACR32927 - Nifedipine

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

Ensure adequate ventilation

#### Environmental precautions

Prevent further leakage or spillage if safe to do so

#### Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid contact with skin and eyes Do not breathe dust Do not breathe vapors or spray mist

#### Conditions for safe storage, including any incompatibilities

Keep container tightly closed Keep refrigerated

#### Specific End Uses

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control parameters **Exposure limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies. **Derived No Effect Level (DNEL)** No information available. **Predicted No Effect Concentration** No information available. (PNEC) **Exposure controls Engineering Measures** Ensure adequate ventilation, especially in confined areas Personal protective equipment **Eve Protection** Goggles Hand Protection Protective aloves Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure **Respiratory Protection** Follow the 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 Handle in accordance with good industrial hygiene and safety practice **Hygiene Measures Environmental exposure controls** No information available.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State Appearance odor pH Boiling Point/Range Powder, Solid Off-white odorless No information available. No information available.

#### ACR32927 - Nifedipine

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Range Flash Point Water Solubility Molecular Formula Molecular Weight 171 - 175°C / 339.8 - 347°F No information available. Insoluble C17 H18 N2 O6 346.3

# **10. STABILITY AND REACTIVITY**

Reactivity Chemical Stability Stable under normal conditions.

Possibility of Hazardous Reactions Hazardous Polymerization Hazardous Reactions .

Hazardous polymerization does not occur. No information available.

Conditions to Avoid Exposure to light, Incompatible products.

Incompatible Materials\_\_\_\_\_ Strong oxidizing agents. Hazardous Decomposition Products

Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

## **11. TOXICOLOGICAL INFORMATION**

#### Information on Toxicological Effects

### Acute Toxicity

**Product Information** 

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

#### **Component Information**

| Component                      | LD50 Oral        | LD50 Dermal | LC50 Inhalation |
|--------------------------------|------------------|-------------|-----------------|
| 3,5-Pyridinedicarboxylic acid, | 1022 mg/kg (Rat) |             |                 |
| 1,4-dihydro-2,6-dimethyl-4-(2- |                  |             |                 |
| nitrophenyl)-, dimethyl ester  |                  |             |                 |

#### **Chronic Toxicity**

Carcinogenicity

There are no known carcinogenic chemicals in this product

| Sensitization                   | No information available.  |
|---------------------------------|--|
| Mutagenic Effects               | No information available   |
| Reproductive Effects            | No information available.  |
| Developmental Effects           | No information available.  |
| Target Organs                   | No information available.  |
| Other Adverse Effects           | The toxicological properties have not been fully investigated. See actual entry in RTECS for |
| Endocrine Disruptor Information | complete information<br>None known   |

# **12. ECOLOGICAL INFORMATION**

Toxicity Ecotoxicity effects

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants

Persistence and degradability No information available Bioaccumulative potential No information available. Mobility in soil No information available. Results of PBT and vPvB assessment Other adverse effects No information available

# **13. DISPOSAL CONSIDERATIONS**

| Waste treatment methodsWaste from Residues / UnusedProductsContaminated PackagingDispose of in accordance with local regulationsEmpty containers should be taken for local recycling, recovery or waste disposal |  |
|--|--|
| <b>Contaminated Packaging</b> Empty containers should be taken for local recycling, recovery or waste disposal   |  |

# 14. TRANSPORT INFORMATION

| IMDG/IMO | Not regulated |
|----------|---------------|
| ADR      | Not regulated |
| ΙΑΤΑ     | Not regulated |

# **15. REGULATORY INFORMATION**

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

| International Inventories           |           |        |     |      |     |      |       |      |       |      |          |
|-------------------------------------|-----------|--------|-----|------|-----|------|-------|------|-------|------|----------|
| Component                           | EINECS    | ELINCS | NLP | TSCA | DSL | NDSL | PICCS | ENCS | CHINA | AICS | KECL     |
| 3,5-Pyridinedicarboxylic acid, 1,4- | 244-598-3 | -      |     | -    | Х   | -    | -     | -    | -     | Х    | KE-10622 |
| dihydro-2,6-dimethyl-4-(2-          |           |        |     |      |     |      |       |      |       |      | Х        |
| nitrophenyl)-, dimethyl ester       |           |        |     |      |     |      |       |      |       |      |          |

Legend

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory **EINECS/ELINCS** - European Inventory Lists **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List **PICCS** - Philippines Inventory of Chemicals and Chemical Substances **ENCS** - Japan Existing and New Chemical Substances **CHINA** - China Inventory of Existing Chemical Substances **AICS** - Inventory of Chemical Substances **KECL** - Existing and Evaluated Chemical Substances

#### **Chemical Safety Assessment**

# **16. OTHER INFORMATION**

Text of R phrases mentioned in Section 2-3 R22 - Harmful if swallowed

Revision Date08-Nov-2010Revision SummaryNot applicableThis safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006Disclaimer

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End of Safety Data Sheet