1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Procardia® (Nifedipine) soft gelatin capsules

Trade Name: Procardia
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
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<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nifedipine</td>
<td>21829-25-4</td>
<td>244-598-3</td>
<td>Acute tox.4 (H302)</td>
<td>2.6</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium saccharin USP</td>
<td>128-44-9</td>
<td>204-886-1</td>
<td>Not Listed</td>
<td>**</td>
</tr>
<tr>
<td>Peppermint oil</td>
<td>8006-90-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol 400</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
**Sodium saccharin is contained in solution for 10 mg capsules only.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:**
Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:**
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

**Nifedipine**
- Pfizer OEL TWA-8 Hr: 300µg/m³

**Polyethylene glycol 400**
- Austria OEL - MAKs 1000 mg/m³
- Germany - TRGS 900 - TWAs 1000 mg/m³
- Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
- Slovakia OEL - TWA 1000 mg/m³
- Slovenia OEL - TWA 1000 mg/m³
- Switzerland OEL -TWAs 1000 mg/m³

**Glycerin, USP**
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Czech Republic OEL - TWA 10 mg/m³
- Estonia OEL - TWA 10 mg/m³
- Finland OEL - TWA 20 mg/m³
- France OEL - TWA 10 mg/m³
- Germany (DFG) - MAK 200 mg/m³
- Greece OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Controls**

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Soft gelatin capsule

**Color:**
- 10 mg: Orange
- 20 mg: Light brown

**Odor:** No data available.

**Molecular Formula:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available.

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

**Partition Coefficient:** (Method, pH, Endpoint, Value)

**Glycerin, USP**
- No data available

**Peppermint oil**
- No data available

**Polyethylene glycol 400**
- No data available

**Sodium saccharin USP**
- No data available

**Nifedipine**
- Measured: N/A
- Log P: 2.20

**Decomposition Temperature (°C):** No data available.
SAFETY DATA SHEET

Material Name: Procardia® (Nifedipine) soft gelatin capsules

Revision date: 04-Oct-2018

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term:
  Antihypertensive drug: has blood pressure-lowering properties
  May cause eye and skin irritation. May be harmful if swallowed. (based on components)
  Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Exposure to sunlight following contact may result in skin reactions.
Known Clinical Effects:
  Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness.

Acute Toxicity: (Species, Route, End Point, Dose)

Glycerin, USP
Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD 50 > 21.9 g/kg

Peppermint oil
Rat Oral LD 50 2426 mg/kg
Mouse Oral LD 50 2490 mg/kg

Sodium saccharin USP
Mouse Oral LD50 17.5 g/kg
11. TOXICOLOGICAL INFORMATION

Acute Toxicity Comments: A greater than symbol (>), indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Glycerin, USP
Eye Irritation Rabbit Mild

Polyethylene glycol 400
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Nifedipine
- 13 Week(s) Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose
- 13 Week(s) Dog Oral 50 mg/kg/day NOAEL No effects at maximum dose
- 4 Week(s) Dog Oral 125 mg/kg/day NOAEL No effects at maximum dose
- 4 Week(s) Dog Intravenous 0.6 mg/kg/day NOAEL No effects at maximum dose
- 1 Year(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nifedipine
- Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Reproductive toxicity, Embryotoxicity, Postnatal mortality, Maternal toxicity
- Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Reproductive toxicity, Fetotoxicity, Maternal Toxicity
- Peri-/Postnatal Development Rat Oral 3 mg/kg/day NOAEL Embryotoxicity
- Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity, Developmental toxicity
- Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Nifedipine
- In Vivo Dominant Lethal Assay Mouse Negative
- In Vivo Cytogenetics Hamster Negative
- In Vivo Micronucleus Mouse Negative
- Bacterial Mutagenicity (Ames) Salmonella Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nifedipine
- 2 Year(s) Rat Oral 156-210 mg/kg/day NOAEL Not carcinogenic
11. TOXICOLOGICAL INFORMATION

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

**Sodium saccharin USP IARC:** Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

**Toxicity:**

**Aquatic Toxicity:** (Species, Method, End Point, Duration, Result)

**Glycerin, USP**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Oncorhynchus mykiss</em> (Rainbow Trout)</td>
<td>LC50</td>
<td>96 Hours</td>
<td>50 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Daphnia magna</em> (Water Flea)</td>
<td>EC50</td>
<td>24 Hours</td>
<td>&gt;500 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

**Nifedipine**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Brachydanio rerio</em> (Zebra fish)</td>
<td>LC50</td>
<td>96 Hours</td>
<td>&gt; 5.77 mg/L</td>
<td></td>
</tr>
<tr>
<td><em>Daphnia magna</em> (Water Flea)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>&gt; 3.88 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

**Aquatic Toxicity Comments:** A greater than symbol (> ) indicates that aquatic toxicity was not observed at the maximum dose tested.

**Bacterial Inhibition:** (Inoculum, Method, End Point, Result)

**Nifedipine**

<table>
<thead>
<tr>
<th>Inoculum</th>
<th>Method</th>
<th>End Point</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated sludge</td>
<td>EC50</td>
<td>&gt; 10000 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Nifedipine**

<table>
<thead>
<tr>
<th>Measured</th>
<th>Log P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>2.20</td>
</tr>
</tbody>
</table>

**Mobility in Soil:** No data available

13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Nifedipine
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 development toxicity 1/29/1999
  Not Listed female reproductive toxicity 1/29/99
  Inventory - United States TSCA - Sect. 8(b)
  Present Australia (AICS):
  Standard for the Uniform Scheduling
  Schedule 4 for Drugs and Poisons:
  EU EINECS/ELINCS List 244-598-3

Sodium saccharin USP
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  EU EINECS/ELINCS List 204-886-1

Peppermint oil
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  EU EINECS/ELINCS List Not Listed

Polyethylene glycol 400
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  Standard for the Uniform Scheduling
  Schedule 2 for Drugs and Poisons:
  Schedule 3
  EU EINECS/ELINCS List Not Listed

Glycerin, USP
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>REACH - Annex V - Exemptions from the obligations of Register:</td>
<td>Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bio accumulative, and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern</td>
</tr>
</tbody>
</table>

EU EINECS/ELINCS List

200-289-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 04-Oct-2018

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet