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

Material Name: Procardia® XL (Nifedipine) tablets

Trade Name: Procardia; Procardia XL
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

2. HAZARDS IDENTIFICATION

Appearance: Round, biconvex, rose-pink film coated tablets

Additional Hazard Information:
Short Term: Dust may cause irritation. May be harmful if swallowed. 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. Antihypertensive drug: has blood pressure-lowering properties

Known Clinical Effects: Adverse effects associated with therapeutic use include decrease in blood pressure (hypotension), headache, dizziness, fatigue, drowsiness, constipation, nausea, gastrointestinal perforation and ulceration.

EU Indication of danger: Not classified


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>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nifedipine</td>
<td>21829-25-4</td>
<td>244-598-3</td>
<td>Xn;R22</td>
<td>11</td>
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<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
MATERIAL SAFETY DATA SHEET

Material Name: Procardia® XL (Nifedipine) tablets
Revision date: 03-Oct-2011

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose Acetate</td>
<td>9004-70-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Opadry YS-5-7017</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene oxide NF</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

4. 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.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
7. HANDLING AND STORAGE

General 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). Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

Ferric oxide red
- ACGIH Threshold Limit Value (TWA) 5 mg/m³
- Australia TWA 5 mg/m³
- Austria OEL - MAKs 5 mg/m³
- Belgium OEL - TWA 2 ppm
- Denmark OEL - TWA 3.5 mg/m³
- Estonia OEL - TWA 3.5 mg/m³
- Finland OEL - TWA 5 mg/m³
- France OEL - TWA 5 mg/m³
- Greece OEL - TWA 10 mg/m³
- Hungary OEL - TWA 6 mg/m³
- Ireland OEL - TWAs 5 mg/m³
- Lithuania OEL - TWA 3.5 mg/m³
- OSHA - Final PELS - TWAs: 10 mg/m³
- Poland OEL - TWA 5 mg/m³
- Portugal OEL - TWA 5 mg/m³
- Romania OEL - TWA 5 mg/m³
- Slovakia OEL - TWA 1.5 mg/m³
- Spain OEL - TWA 5 mg/m³
- Sweden OEL - TWAs 3.5 mg/m³

Polyethylene oxide NF
- Austria OEL - MAKs 1000 mg/m³
- Germany - TRGS 900 - TWAs 1000 mg/m³
- Germany (DFG) - MAK 1000 mg/m³ inhalable fraction
- Slovakia OEL - TWA 1000 mg/m³
- Slovenia OEL - TWA 1000 mg/m³

Sodium chloride
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th></th>
<th>Varies by country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nifedipine</td>
<td></td>
</tr>
<tr>
<td>Polymerization</td>
<td>Will not occur</td>
</tr>
</tbody>
</table>

**Analytical Method:**
Analytical method available for Nifedipine. Contact Pfizer Inc for further information.

**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.

**Environmental Exposure Controls:**
Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:**
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:**
Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:**
Wear safety glasses or goggles if eye contact is possible.

**Skin:**
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:**
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:**
Tablet

**Molecular Formula:**
Mixture

**Color:**
Rose-pink

**Molecular Weight:**
Mixture

**Polymerization:**
Will not occur

10. STABILITY AND REACTIVITY

**Chemical Stability:**
Stable under normal conditions of use.

**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

11. TOXICOLOGICAL INFORMATION

**General Information:**
The information included in this section describes the potential hazards of the individual ingredients.
11. TOXICOLOGICAL INFORMATION

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

Hydroxypropyl methylcellulose
Rat  Oral  LD50  > 10,000 mg/kg

Magnesium stearate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 2000 mg/m³

Nifedipine
Mouse  Oral  LD50  454 mg/kg
Rat  Oral  LD50  1022 mg/kg
Mouse  IV  LD50  4.2 mg/kg
Rat  IV  LD50  15.5 mg/kg

Sodium chloride
Rat  Oral  LD50  3000 mg/kg
Mouse  Oral  LD50  4000 mg/kg

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)

Polyethylene glycol
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Polyethylene oxide NF
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Sodium chloride
Eye Irritation  Rabbit  Moderate
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
Subchronic intravenous and oral toxicity studies revealed no drug-related effects in general behavior, clinical laboratory tests, gross necropsy, or histopathology in any of the dog and rat studies. Oral doses administered demonstrated nifedipine to be without significant toxic effects at doses up to 100 - 125 mg/kg/day.

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
11. TOXICOLOGICAL INFORMATION

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

Ferric oxide red
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.

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

Nifedipine
- Brachydanio rerio (Zebra fish) LC50 96 Hours > 5.77 mg/L
- Daphnia magna (Water Flea) EC50 48 Hours > 3.88 mg/L

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
- Activated sludge EC50 0.5 Hours > 10000 mg/L

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

EU Indication of danger: Not classified

OSHA Label:

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Nifedipine

California Proposition 65
developmental toxicity initial date 1/29/99
female reproductive toxicity 1/29/99
male reproductive toxicity initial date 1/29/99

Australia (AICS):
Present

Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 4

EU EINECS/ELINCS List
244-598-3

Cellulose Acetate

Inventory - United States TSCA - Sect. 8(b)
Present

Australia (AICS):
Present

Ferric oxide red

Inventory - United States TSCA - Sect. 8(b)
Present

Australia (AICS):
Present

EU EINECS/ELINCS List
215-168-2

Polyethylene oxide NF

Inventory - United States TSCA - Sect. 8(b)
Present

Australia (AICS):
Present

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)
Present

Australia (AICS):
Present

EU EINECS/ELINCS List
231-598-3
15. REGULATORY INFORMATION

Polyethylene glycol
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present

Hydroxypropyl methylcellulose
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  Standard for the Uniform Scheduling for Drugs and Poisons:  Schedule 4

Magnesium stearate
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS/ELINCS List  209-150-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
Data Sources:  Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision:  Updated Section 2 - Hazard Identification.
Prepared by:  Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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