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

Product Identifier

Material Name: Verapamil HCl Caplets, Sustained Release
Trade Name: CALAN SR
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as Anti-anginal; anti-hypertensive.

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 3
Reproductive Toxicity: Category 2
Acute aquatic toxicity: Category 2
Chronic aquatic toxicity: Category 2

Label Elements

Signal Word: Danger
Hazard Statements:
H301 - Toxic if swallowed
H361d - Suspected of damaging the unborn child
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects
Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P281 - Use personal protective equipment as required
P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P330 - Rinse mouth
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Verapamil Hydrochloride</td>
<td>152-11-4</td>
<td>205-800-5</td>
<td>Acute Tox. 3, H301</td>
<td>30-34</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. 2, H361dAcute</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2, H401 Chronic 2, H411</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opadry</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Opadry Pink</td>
<td>MIXTURE</td>
<td>Not Listed</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>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium alginate</td>
<td>9005-38-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion: 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

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.
7. HANDLING AND STORAGE

Precautions for Safe Handling
If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium Stearate
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³

Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
5 mg/m³

Polyethylene glycol

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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Verapamil Hydrochloride**  
**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

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

- **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:** Film-coated Caplets  
- **Color:** Pink or green.  
- **Odor:** No data available.  
- **Odor Threshold:** No data available.  
- **Molecular Formula:** Mixture  
- **Molecular Weight:** 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)

- **Magnesium Stearate:** No data available
- **Sodium alginate:** No data available
- **Povidone:** No data available
- **Carnauba wax:** No data available

CALAN SR
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Opadry
No data available

Polyethylene glycol
No data available

Microcrystalline cellulose
No data available

Verapamil Hydrochloride
Measured Log P 3.79

Decomposition Temperature (°C): No data available.

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

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: Not expected to cause skin irritation, eye irritation (based on components).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver (based on components).

Known Clinical Effects: May cause low blood pressure and dizziness. Occasional, transient changes reported in liver function tests, but no liver damage seen. This material has been shown to be secreted in low concentrations in human breast milk.

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

Povidone
Rat Oral LD50 100 g/kg

Microcrystalline cellulose
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)**

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Microcrystalline cellulose**

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Eye Irritation**

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate</td>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>1092</td>
<td>LOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verapamil Hydrochloride</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>55</td>
<td>mg/kg/day</td>
<td>NOAEL</td>
<td>Fertility</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>60</td>
<td>mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>60</td>
<td>mg/kg/day</td>
<td>LOAEL</td>
<td>Fetotoxicity</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>15</td>
<td>mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verapamil Hydrochloride</td>
<td></td>
<td>Salmonella, E. coli</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verapamil Hydrochloride</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>58</td>
<td>mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
<tr>
<td>2 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>120</td>
<td>mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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

Povidone
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic life with long lasting effects. See Aquatic toxicity data of the active ingredient, below:

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

Verapamil Hydrochloride
*Oncorhynchus mykiss* (Rainbow Trout)  LC50  96 Hours  2.72 mg/L
*Daphnia magna* (Water Flea)  LC50  48 Hours  7.04 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Verapamil Hydrochloride
*Pimephales promelas* (Fathead Minnow)  OECD 28 Day(s)  NOEC 0.3 mg/L  Growth
*Pimephales promelas* (Fathead Minnow)  OECD 28 Day(s)  NOEC 0.6 mg/L  Survival

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Verapamil Hydrochloride
Measured  Log P  3.79

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

Magnesium Stearate
- 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: 209-150-3

Microcrystalline cellulose
- 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: 232-674-9

Opadry
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Opadry Pink
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Polyethylene glycol
- 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 for Drugs and Poisons:
  - Schedule 2
  - Schedule 3
- EU EINECS/ELINCS List: Not Listed

Povidone
- 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

Sodium alginate
15. REGULATORY INFORMATION

| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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 |

Verapamil Hydrochloride

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 205-800-5 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
- Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
- Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

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

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

Revision date: 23-May-2018

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