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

Product Identifier

Material Name: Verapamil Hydrochloride Tablets
Trade Name: CALAN
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
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)
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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Verapamil Hydrochloride</td>
<td>152-11-4</td>
<td>205-800-5</td>
<td>Acute Tox. 3, H301 Repr. 2, H361dAcute 2,H401Chronic 2,H411</td>
<td>33-37</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</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>
</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>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose hydrous</td>
<td>64044-51-5</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>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Verapamil Hydrochloride Tablets
Revision date: 23-May-2018

Additional Information:
* Proprietary
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: 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.

Products: Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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.
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). 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.

Corn Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
           5 mg/m³
Ireland OEL - TWAs 10 mg/m³
           4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Talc (non-asbestiform)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm3
           6.0 mg/m³
           3.0 mg/m³
Czech Republic OEL - TWA 2.0 mg/m³
Denmark OEL - TWA 0.3 fiber/cm3
Finland OEL - TWA 0.5 fiber/cm3
Greece OEL - TWA 10 mg/m³
           2 mg/m³
Hungary OEL - TWA 2 mg/m³
Ireland OEL - TWAs 10 mg/m³
           0.8 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: Verapamil Hydrochloride Tablets</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8. EXPOSURE CONTROLS / PERSONAL PROTECTION</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lithuania OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td><strong>Netherlands OEL - TWA</strong></td>
<td>0.25 mg/m³</td>
</tr>
<tr>
<td><strong>OSHA - Final PELs - Table Z-3 Mineral D:</strong></td>
<td>20 mppcf</td>
</tr>
<tr>
<td><strong>Poland OEL - TWA</strong></td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td><strong>Portugal OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Romania OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Slovakia OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Slovenia OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Spain OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Sweden OEL - TWAs</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td><strong>Switzerland OEL -TWAs</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Magnesium Stearate</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lithuania OEL - TWA</strong></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Sweden OEL - TWAs</strong></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Microcrystalline cellulose</strong></td>
<td></td>
</tr>
<tr>
<td><strong>ACGIH Threshold Limit Value (TWA)</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Australia TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Belgium OEL - TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Estonia OEL - TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>France OEL - TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Ireland OEL - TWAs</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td><strong>Latvia OEL - TWA</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>OSHA - Final PELS - TWAs:</strong></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td><strong>Portugal OEL - TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Romania OEL - TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Russia OEL - TWA</strong></td>
<td>6 mg/m³</td>
</tr>
<tr>
<td><strong>Spain OEL - TWA</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Switzerland OEL -TWAs</strong></td>
<td>3 mg/m³</td>
</tr>
<tr>
<td><strong>Vietnam OEL - TWAs</strong></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Polyethylene glycol</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Austria OEL - MAKs</strong></td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td><strong>Germany - TRGS 900 - TWAs</strong></td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td><strong>Germany (DFG) - MAK</strong></td>
<td>1000 mg/m³ average molecular weight 200-600</td>
</tr>
<tr>
<td><strong>Slovakia OEL - TWA</strong></td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td><strong>Slovenia OEL - TWA</strong></td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td><strong>Switzerland OEL -TWAs</strong></td>
<td>1000 mg/m³</td>
</tr>
</tbody>
</table>

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** OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

**Band (OEB):**
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: Film-coated tablets
Odor: No data available.
Molecular Formula: Mixture

Color: Pink, peach, or brown.
Odor Threshold: No data available.
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) Polyethylene glycol

No data available
Magnesium Stearate
No data available
Corn Starch
No data available
Microcrystalline cellulose
No data available
Gelatin
No data available
Verapamil Hydrochloride
Measured Log P  3.79
Talc (non-asbestiform)
No data available
Hydroxypropyl methylcellulose
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Lactose hydrous
No data available

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)

Microcrystalline cellulose
  Rat Oral LD50 > 5000 mg/kg
  Rabbit Dermal LD50 > 2000 mg/kg

Verapamil Hydrochloride
  Rat Oral LD50 108 mg/kg
  Mouse Oral LD50 163 mg/kg
  Rat Intravenous LD50 16 mg/kg
  Mouse Intravenous LD50 5795 mg/kg
  Rat Subcutaneous LD50 107 mg/kg
11. TOXICOLOGICAL INFORMATION

**Talc (non-asbestiform)**
Rat  Oral  LD50  >  1600 mg/kg

**Hydroxypropyl methylcellulose**
Rat  Oral  LD50  > 10,000 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

- **Microcrystalline cellulose**
  - Skin Irritation  Rabbit  Non-irritating
  - Eye Irritation  Rabbit  Non-irritating

**Verapamil Hydrochloride**
Skin Irritation  Rabbit  Mild

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

- **Magnesium Stearate**
  - 13 Week(s)  Rat  Oral  1092 g/kg  LOAEL  Liver

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

- **Verapamil Hydrochloride**
  - Reproductive & Fertility  Rat  Oral  55 mg/kg/day  NOAEL  Fertility
  - Embryo / Fetal Development  Rat  Oral  60 mg/kg/day  NOAEL  Not Teratogenic
  - Embryo / Fetal Development  Rat  Oral  60 mg/kg/day  LOAEL  Fetotoxicity
  - Embryo / Fetal Development  Rabbit  Oral  15 mg/kg/day  NOAEL  Not Teratogenic

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

- **Verapamil Hydrochloride**
  - Bacterial Mutagenicity (Ames)  *Salmonella*, *E. coli*  Negative

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

- **Verapamil Hydrochloride**
  - 18 Month(s)  Rat  Oral  58 mg/kg/day  NOAEL  Not carcinogenic
  - 2 Year(s)  Rat  Oral  120 mg/kg/day  NOAEL  Not carcinogenic

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

**Talc (non-asbestiform)**
IARC: Group 3 (Not Classifiable)
11. TOXICOLOGICAL INFORMATION

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

**Corn Starch**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register:
  - EU EINECS/ELINCS List: 232-679-6

**Gelatin**
- 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: 232-554-6

**Lactose hydrous**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

**Talc (non-asbestiform)**
- 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: 238-877-9

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

**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
15. REGULATORY INFORMATION

| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-674-9 |

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
- EU EINECS/ELINCS List: Not Listed

Hydroxypropyl methylcellulose
- 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 4
- EU EINECS/ELINCS List: Not Listed

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. Publicly available toxicity information.

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 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