SAFETY DATA SHEET

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.

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

EU Classification:

EU Indication of danger: Toxic

Toxic to Reproduction: Category 3
Dangerous for the Environment

EU Risk Phrases:

R25 - Toxic if swallowed.
R63 - Possible risk of harm to the unborn child.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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)
- P391 - Collect spillage
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

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 Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Verapamil Hydrochloride</td>
<td>152-11-4</td>
<td>205-800-5</td>
<td>T; R25Cat.3, R63;R51/53 Acute Tox. 3, H301 Repr. 2, H361dAcute 2,H401Chronic 2,H411</td>
<td>33-37</td>
<td></td>
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<tr>
<td>Microcrystalline cellulose</td>
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<td>209-150-3</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
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<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Gelatin</td>
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<td>Lactose hydrous</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
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<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</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.
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 R phrases and 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 Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters
During all fire fighting 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. Clean up 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). 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>Substance</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs:</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 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

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CALAN
## 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).

**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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Film-coated tablets</td>
<td>Color</td>
<td>Pink, peach, or brown.</td>
</tr>
<tr>
<td>Odor</td>
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<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
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<tr>
<td>Boiling Point (°C)</td>
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<td>Partition Coefficient: (Method, pH, Endpoint, Value) Polyethylene glycol</td>
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<tr>
<td>Magnesium Stearate</td>
<td>No data available</td>
<td>Corn Starch</td>
<td>No data available</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>No data available</td>
<td>Gelatin</td>
<td>No data available</td>
</tr>
<tr>
<td>Verapamil Hydrochloride</td>
<td>Measured Log P 3.79</td>
<td>Verapamil (non-asbestiform)</td>
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</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>No data available</td>
<td>Hydroxypropyl methylcellulose</td>
<td>No data available</td>
</tr>
<tr>
<td>Lactose hydrous</td>
<td>No data available</td>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
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<td></td>
</tr>
</tbody>
</table>
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 LD 50 108 mg/kg
- Mouse Oral LD 50 163 mg/kg
- Rat Intravenous LD 50 16 mg/kg
- Mouse Intravenous LD 50 5795 mg/kg
- Rat Subcutaneous LD 50 107 mg/kg

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.
11. TOXICOLOGICAL INFORMATION

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)

12. ECOLOGICAL INFORMATION

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

Toxicity:  CALAN
SAFETY DATA SHEET

Material Name: Verapamil Hydrochloride Tablets
Revision date: 17-Feb-2015

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision B
Class D, Division 2, Subdivision A

CALAN
15. REGULATORY INFORMATION

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: | Present |
| 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   |
| REACH - Annex IV - Exemptions from the obligations of Register: | 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 |

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 |

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   |
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>EU EINECS/ELINCS List</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</th>
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<tbody>
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<td>Not Listed</td>
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<td>Use restricted. See item 9[f], powder</td>
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<tr>
<td>Verapamil Hydrochloride</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>205-800-5</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>232-674-9</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases and 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

T - Toxic
N - Dangerous for the environment
Toxic to Reproduction: Category 3

R25 - Toxic if swallowed.
R63 - Possible risk of harm to the unborn child.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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 7 - Handling and Storage. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information. Updated Section 11 - Toxicology Information.

Revision date: 17-Feb-2015
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