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

Material Name: Pristiq Tablets

Trade Name: PRISTIQ
Synonyms: Desvenlafaxine Succinate Extended Release Tablets
Chemical Family: Serotonin Noradrenaline Reuptake Inhibitor
Intended Use: Pharmaceutical product used as antidepressant

2. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:

Short Term: Individuals taking monoamine oxidase (MAO) inhibitors should avoid exposure to this material.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, insomnia, nausea, constipation, vomiting, dry mouth, nervousness, anxiety, tremors, impotence, abnormal dreams, abnormal ejaculation, and sweating. Signs and symptoms associated with non-fatal overdosage were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

EU Indication of danger: Harmful

EU Hazard Symbols: 

EU Risk Phrases: R22 - Harmful if swallowed.

2. HAZARDS IDENTIFICATION

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>Desvenlafaxine Succinate Monohydrate</td>
<td>386750-22-7</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>50-200mg***</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Iron oxide</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
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<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
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: Formation of toxic gases is possible during heating or fire.

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

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Fire / Explosion Hazards: Strong dust explosion characteristic. High sensitivity of a dust cloud to ignition, based on minimum ignition energy.

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 spill with absorbent material. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion characteristic and high sensitivity to ignition.

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 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Desvenlafaxine Succinate Monohydrate
Pfizer OEL TWA-8 Hr: 350µg/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
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
Spain OEL - TWA 10 mg/m³

Iron oxide
ACGIH Threshold Limit Value (TWA) 5 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>OEL/TWA Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Magnesium stearate</strong></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>3.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td><strong>Polyethylene glycol</strong></td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ inhalable fraction</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong></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>
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<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
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<td>Greece OEL - TWA</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
</tbody>
</table>

Material Name: Pristiq Tablets

Revision date: 23-Oct-2011

Version: 5.0
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Limit Value (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portugal OEL - TWA</td>
<td>10</td>
</tr>
<tr>
<td>Romania OEL - TWAs</td>
<td>10</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit</td>
<td>2</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0</td>
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<tr>
<td>Czech Republic OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.3</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.5</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2</td>
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<td>Netherlands OEL - TWA</td>
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<tr>
<td>OSHA - Final PELs - Table</td>
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<tr>
<td>Poland OEL - TWA</td>
<td>4.0</td>
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<tr>
<td>Portugal OEL - TWAs</td>
<td>2</td>
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<tr>
<td>Romania OEL - TWA</td>
<td>2</td>
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<tr>
<td>Slovakia OEL - TWA</td>
<td>2</td>
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<tr>
<td>Slovenia OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2</td>
</tr>
</tbody>
</table>

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: Tablets
Molecular Formula: Mixture
Color: Various
Molecular Weight: Mixture

Water solubility: 30 mg/mL
Melting/Freezing Point (°C): 105
Partition Coefficient (Measured - Log Pow/Log Kow): 0.33 (desvenlafaxine succinate monohydrate)

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The following information describes the toxicity of a chemically-related material. The toxicities of the two materials can be expected to be similar.

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

Venlafaxine hydrochloride
Rat (M) Oral LD50 700 mg/kg  
Rat (F) Oral LD50 350 mg/kg

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

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

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

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m²

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

Desvenlafaxine Succinate Monohydrate
Rat IP Minimum Lethal Dose 700 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)

**O-Desmethylvenlafaxine free base**
- Skin Corrosivity (*In vitro*, RHE)  Negative
- Eye Irritation (*In vitro*, BCOP)  Negative
- Skin Sensitization - LLNA  Mouse  Negative

**Venlafaxine hydrochloride**
- Eye Irritation (*In vitro*, BCOP)  Negative

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

**Polyethylene glycol**
- Eye Irritation  Rabbit  Mild
- Skin Irritation  Rabbit  Mild

**Desvenlafaxine Succinate Monohydrate**
- Skin Corrosivity (*In vitro*, RHE)  Negative
- Eye Irritation (*In vitro*, BCOP)  Negative
- Skin Sensitization - LLNA  Mouse  Negative

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

**Desvenlafaxine Succinate Monohydrate**
- 6 Month(s)  Rat  Oral  300 mg/kg/day  LOAEL  None identified
- 9 Month(s)  Dog  Oral  50 mg/kg/day  NOAEL  No effects at maximum dose

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

**O-Desmethylvenlafaxine free base**
- Fertility and Embryonic Development  Rat  Oral  30 mg/kg/day  NOAEL  Fertility
- Fertility and Embryonic Development  Rat  Oral  100 mg/kg/day  NOAEL  Developmental toxicity

**Venlafaxine hydrochloride**
- Reproductive & Fertility  Rat  Oral  8 times human dose  NOAEL  No effects at maximum dose
- Embryo / Fetal Development  Rabbit  Oral  12 times human dose  NOAEL  Not Teratogenic
- Embryo / Fetal Development  Rat  Oral  1.4 times human dose  NOAEL  Not Teratogenic, Neonatal toxicity

**Desvenlafaxine Succinate Monohydrate**
- Fertility and Embryonic Development  Rat  Oral  30 mg/kg/day  NOAEL  Fertility
- Fertility and Embryonic Development  Rat  Oral  100 mg/kg/day  NOAEL  Developmental toxicity
- Embryo / Fetal Development  Rabbit  Oral  75 mg/kg/day  NOAEL  No effects at maximum dose

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

**O-Desmethylvenlafaxine free base**
- *In Vitro* Bacterial Mutagenicity (Ames)  *Salmonella*  Negative
- *In Vitro* Micronucleus  Mouse  Negative
- Forward Mutation Assay  Chinese Hamster Ovary (CHO) cells  Negative
- *In Vivo* Chromosome Aberration  Rat  Equivocal
11. TOXICOLOGICAL INFORMATION

Venlafaxine hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella  Negative
Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative
In Vitro Cell Transformation Assay  Mouse  Negative
In Vitro Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Negative
In Vivo Chromosome Aberration  Rat Bone Marrow  Negative

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

Venlafaxine hydrochloride
18 Month(s)  Mouse  Oral  120 mg/kg/day  NOAEL  Not carcinogenic
24 Month(s)  Rat  Oral  120 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

Polyvinyl alcohol
IARC: Group 3 (Not Classifiable)

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

Iron oxide
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The information in this section includes the potential hazards of a chemically related material. The toxicities of the two materials can be expected to be similar to aquatic organisms. The Partition Coefficient (Measured - Log Pow/Log Kow): 0.33 (desvenlafaxine succinate monohydrate)

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

Venlafaxine hydrochloride
Daphnia magna (Water Flea)  EC50  48 Hours  38 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD EC50  72 Hours  4.8 mg/L
Onchorhyncus mykiss (Rainbow Trout)  OECD LC50  96 Hours  > 100 mg/L

Desvenlafaxine Succinate Monohydrate
Daphnia magna (Water Flea)  OECD EC50  48 Hours  33 mg/L
Pimephales promelas (Fathead Minnow)  OECD LC50  96 Hours  9.4 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD EC50  72 Hours  32.2 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)
12. ECOLOGICAL INFORMATION

Desvenlafaxine Succinate Monohydrate
Activated sludge  OECD  EC50  3 Hours  > 100 mg/L

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

Desvenlafaxine Succinate Monohydrate
Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 8.2 mg/L Reproduction
Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 2.1 mg/L Growth

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 Symbol: Xn
EU Indication of danger: Harmful
EU Risk Phrases: R22 - Harmful if swallowed.
EU Safety Phrases: S22 - Do not breathe dust.

OSHA Label:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications
15. REGULATORY INFORMATION

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.

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

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

Iron oxide
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present

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

Polyvinyl alcohol
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present

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

Titanium dioxide
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

Talc (non-asbestiform)
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 238-877-9

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information.
Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage. Updated Section 12 - Ecological Information.

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