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

Product Identifier

Material Name: Pristiq Tablets

Trade Name: PRISTIQ; ECENZE; ELLEFORE; ENZUDE; EXSIRA

Synonyms: Desvenlafaxine Succinate Extended Release Tablets

Chemical Family: Serotonin Noradrenaline Reuptake Inhibitor

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

Intended Use: Pharmaceutical product used as antidepressant

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Acute aquatic toxicity: Category 3

EU Classification:
EU Indication of danger: Harmful
EU Risk Phrases:
R22 - Harmful if swallowed.

Label Elements

Signal Word: Warning
Hazard Statements:
H302 - Harmful if swallowed
H402 - Harmful to aquatic life

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P273 - Avoid release to the environment
P501 - Dispose of contents/container in accordance with all local and national regulations
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>GHS 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>Acute Tox.4 (H302) Aquatic Acute 3 (H402)</td>
<td>45</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</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>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>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>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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards: Strong dust explosion characteristic. High sensitivity of a dust cloud to ignition, based on minimum ignition energy.

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 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.
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.

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.

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
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³

Iron oxide
ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 2 ppm
Bulgaria OEL - TWA 5.0 mg/m³
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
Russia OEL - TWA 6 mg/m³
Slovakia OEL - TWA 1.5 mg/m³
Spain OEL - TWA 5 mg/m³
Sweden OEL - TWAs 3.5 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Concentration (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

**Magnesium stearate**
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 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 ppm

**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
- Lithuania OEL - TWA: 2 mg/m³
  - 1 mg/m³
- Netherlands OEL - TWA: 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA: 4.0 mg/m³
  - 1.0 mg/m³
- Portugal OEL - TWA: 2 mg/m³
- Romania OEL - TWA: 2 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
  - 10 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
- Spain OEL - TWA: 2 mg/m³
- Sweden OEL - TWAs: 2 mg/m³
  - 1 mg/m³
- Switzerland OEL - TWAs: 2 mg/m³

**Titanium dioxide**
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- ACGIH OELs - Notice of Intended Changes: Listed
- Australia TWA: 10 mg/m³
- Austria OEL - MAKs: 5 mg/m³
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 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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>Various</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Solvent Solubility:</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water solubility:</td>
<td>30 mg/mL</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>105</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Venlafaxine hydrochloride</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Polyvinyl alcohol
No data available
Titanium dioxide
No data available
Iron oxide
No data available
Polyethylene glycol
No data available
Hydroxypropyl methylcellulose
No data available
Magnesium stearate
No data available
O-Desmethylvenlafaxine free base
Predicted 7.0 Log P 2.26
Microcrystalline cellulose
No data available
Desvenlafaxine Succinate Monohydrate
Measured 6.0 Log P 0.33
Talc (non-asbestiform)
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

Polymerization: Will not occur

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: Keep away from heat and other sources of ignition, including electrostatic discharge.
- 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 following information describes the toxicity of a chemically-related material. The toxicities of the two materials can be expected to be similar.

Short Term: Individuals taking monoamine oxidase (MAO) inhibitors should avoid exposure to this material.
11. TOXICOLOGICAL INFORMATION

**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.

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Venlafaxine hydrochloride</strong></td>
<td>Oral</td>
<td>LD50</td>
<td>700 mg/kg</td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong></td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 7500 mg/kg</td>
</tr>
<tr>
<td><strong>Hydroxypropyl methylcellulose</strong></td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 10,000 mg/kg</td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td><strong>Microcrystalline cellulose</strong></td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td><strong>Desvenlafaxine Succinate Monohydrate</strong></td>
<td>IP</td>
<td>Minimum Lethal Dose</td>
<td>700 mg/kg</td>
</tr>
<tr>
<td><strong>Talc (non-asbestiform)</strong></td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 1600 mg/kg</td>
</tr>
</tbody>
</table>

**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 Name</th>
<th>Study Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Polyethylene glycol</strong></td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
</tr>
<tr>
<td><strong>Microcrystalline cellulose</strong></td>
<td>Skin Sensitization - LLNA</td>
<td>Mouse</td>
<td>Negative</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

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))

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

Venlafaxine hydrochloride
Embryo / Fetal Development  Rat  Oral 1.4 times human dose  NOAEL  Not Teratogenic, Neonatal toxicity

O-Desmethylenlafaxine 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

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)

Venlafaxine hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella  Negative
Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative

Venlafaxine hydrochloride
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

O-Desmethylenlafaxine free base
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative

O-Desmethylenlafaxine free base
In Vitro Micronucleus  Mouse  Negative
Forward Mutation Assay  Chinese Hamster Ovary (CHO) cells  Negative
In Vivo Chromosome Aberration  Rat  Equivocal

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
11. TOXICOLOGICAL INFORMATION

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.

Polyvinyl alcohol
   IARC: Group 3 (Not Classifiable)

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

Iron oxide
   IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)
   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 Toxic to aquatic organisms.

Toxicity:

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

Venlafaxine hydrochloride
   Daphnia magna (Water Flea) OECD EC50 48 Hours 38 mg/L
   Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 4.8 mg/L
   Oncorhynchus 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)

Desvenlafaxine Succinate Monohydrate
   Activated sludge OECD EC50 > 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
   Chironomus riparius (Sediment-Dwelling Midge) OECD 28 Day(s) NOEC 52 mg/kg

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Partition Coefficient: (Method, pH, Endpoint, Value)
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:
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.

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

Hydroxypropyl methylcellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</td>
<td>Use restricted. See item 9(f). powder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>232-674-9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron oxide</td>
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Material Name: Pristiq Tablets
Revision date: 23-Feb-2015
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Version: 6.0
15. REGULATORY INFORMATION

Titanium dioxide

**CERCLA/SARA 313 Emission reporting**  Not Listed
**California Proposition 65**  carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
**Inventory - United States TSCA - Sect. 8(b)**  Present
**Australia (AICS):**  Present
**EU EINECS/ELINCS List**  236-675-5

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Xn - Harmful

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 7 - Handling and Storage. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

**Revision date:**  23-Feb-2015

**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**