SAFETY DATA SHEET

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

Product Identifier

Material Name: Venlafaxine Hydrochloride Modified Release Capsules

Trade Name: EFFEXOR: TREVILOR; ALTVEN; EFECTIN; EFEXOR; EFFEXOR XR; EFEXOR XR; FAXINE; DOBUPAL

Chemical Family: Serotonin Noradrenaline Reuptake Inhibitor

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

Intended Use: Pharmaceutical active 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

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 4
Acute aquatic toxicity: Category 2

Label Elements

Signal Word: Warning
Hazard Statements:
H302 - Harmful if swallowed
H401 - Toxic 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
P501 - Dispose of contents/container in accordance with all local and national regulations
P273 - Avoid release to the environment
P391 - Collect spillage
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>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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<td>*</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
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<tr>
<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>Not Listed</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Venlafaxine hydrochloride</td>
<td>99300-78-4</td>
<td>Not Listed</td>
<td>Acute Tox.4 (H302)</td>
<td>30-40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 2 (H401)</td>
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</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>
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<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
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<tr>
<td>Black Iron Oxide</td>
<td>1317-61-9</td>
<td>215-277-5</td>
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</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Ethylcellulose</td>
<td>9004-57-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</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 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 hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Talc (non-asbestiform)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 fiber/cm³ to 6.0 mg/m³ to 3.0 mg/m³</td>
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</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>2.0 mg/m³</td>
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</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.3 fiber/cm³</td>
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</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.5 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³ to 2 mg/m³</td>
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</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
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</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³ to 0.8 mg/m³</td>
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<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
<td>1 mg/m³</td>
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<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
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<td>Poland OEL - TWA</td>
<td>4.0 mg/m³ to 1.0 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>2 mg/m³</td>
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</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³ to 10 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³ to 1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 mg/m³</td>
<td></td>
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</tbody>
</table>

Titanium dioxide

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<table>
<thead>
<tr>
<th></th>
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<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
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<td>ACGIH OELs - Notice of Intended Changes</td>
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<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Austria OEL - MAKs</td>
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<td>10 mg/m³</td>
<td></td>
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<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
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<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
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<tr>
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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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<th>Value</th>
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<td>Latvia OEL - TWA</td>
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<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
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<td>Russia OEL - TWA</td>
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<td>10 mg/m³</td>
<td></td>
</tr>
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<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
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<tr>
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#### Ferric oxide red

<table>
<thead>
<tr>
<th>Country</th>
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<th>Value</th>
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<tbody>
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<tr>
<td>10 mg/m³</td>
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<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
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<td></td>
</tr>
<tr>
<td>10 mg/m³</td>
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<tr>
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<td>10 mg/m³</td>
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<tr>
<td>4 mg/m³</td>
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<td>15 mg/m³</td>
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<tr>
<td>Sweden OEL - TWAs</td>
<td>3.5 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
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</tbody>
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#### Microcrystalline cellulose

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL or MAK</th>
<th>Value</th>
</tr>
</thead>
<tbody>
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<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
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<tr>
<td>Australia TWA</td>
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<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
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</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>
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

Physical State: Hard-gelatin Capsule

Color: Light grey, Peach, or Dark orange

Odor: No data available.

Odor Threshold: No data available.

Molecular Formula: Mixture

Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: No data available

pH: No data available.

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available

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

Ferric oxide yellow
No data available

Microcrystalline cellulose
No data available

Ferric oxide red
No data available

Ethylcellulose
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Hydroxypropyl methylcellulose
No data available

Gelatin
No data available

Talc (non-asbestiform)
No data available

Titanium dioxide
No data available

Black Iron Oxide
No data available

Venlafaxine hydrochloride
Measured Log P 0.5

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: 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: 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, constipation, vomiting, dry mouth, nervousness, nausea, anxiety, sweating, abnormal dreams, tremors, abnormal ejaculation, and impotence. Signs and symptoms associated with non-fatal overdosage were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.
11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

**Black Iron Oxide**
- Rat  Oral  LD50  >1000 mg/kg

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

**Irritation / Sensitization: (Study Type, Species, Severity)**

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

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

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

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

**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))**
11. TOXICOLOGICAL INFORMATION

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 of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Ferric oxide red
IARC: Group 3 (Not Classifiable)

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic organisms.

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
_Onchorhynchus mykiss_ (Rainbow Trout) OECD LC50 96 Hours > 100 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Partition Coefficient: (Method, pH, Endpoint, Value)
Venlafaxine hydrochloride
Measured Log P 0.5

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

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

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

Titanium dioxide
- 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: 236-675-5

Ferric oxide red
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present

Black Iron Oxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</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>
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</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
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<td>Ferric oxide yellow</td>
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<td>Hydroxypropyl methylcellulose</td>
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<td>Venlafaxine hydrochloride</td>
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<td>Present</td>
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</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.
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