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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
</tbody>
</table>

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

### Material Name: Venlafaxine Hydrochloride Modified Release Capsules

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>EFFEXOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Serotonin Noradrenaline Reuptake Inhibitor</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical active used as antidepressant</td>
</tr>
</tbody>
</table>

### 2. HAZARDS IDENTIFICATION

| Appearance: | Light grey peach or dark orange hard gelatin capsules |
| 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, 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.

**EU Indication of danger:** Harmful

**EU Hazard Symbols:**

**EU Risk Phrases:** R22 - Harmful if swallowed.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**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.
2. HAZARDS IDENTIFICATION

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>Venlafaxine hydrochloride</td>
<td>99300-78-4</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>30-40</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>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</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>*</td>
</tr>
<tr>
<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ethylcellulose</td>
<td>9004-57-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Black Iron Oxide</td>
<td>1317-61-9</td>
<td>215-277-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: 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.

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 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.

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.

Venlafaxine hydrochloride
- Pfizer OEL TWA-8 Hr: 250µg/m³

Microcrystalline cellulose
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Estonia OEL - TWA: Listed
- France OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- Latvia OEL - TWA: Listed
- OSHA - Final PELS - TWAs: 15 mg/m³ total
  5 mg/m³
- Portugal OEL - TWA: Listed
- Romania OEL - TWA: Listed
- Spain OEL - TWA: Listed

Talc (non-asbestiform)
- ACGIH Threshold Limit Value (TWA): 2 mg/m³ TWA
- ACGIH OELs - Notice of Intended Changes: Listed
- Australia TWA: 2.5 mg/m³ containing no asbestos fibers
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>MAKs</td>
<td>Listed</td>
</tr>
<tr>
<td>Belgium</td>
<td>TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Denmark</td>
<td>TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Estonia</td>
<td>TWA</td>
<td>Listed</td>
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<tr>
<td>Finland</td>
<td>TWA</td>
<td>Listed</td>
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<tr>
<td>Greece</td>
<td>TWA</td>
<td>Listed</td>
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<tr>
<td>Hungary</td>
<td>TWA</td>
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<tr>
<td>Ireland</td>
<td>TWAs</td>
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<tr>
<td>Netherlands</td>
<td>TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA</td>
<td>Final PELs</td>
<td>Listed</td>
</tr>
<tr>
<td>Poland</td>
<td>TWA</td>
<td>Listed</td>
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<tr>
<td>Portugal</td>
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<td>Romania</td>
<td>TWA</td>
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<td>Slovenia</td>
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<td>Spain</td>
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</tr>
<tr>
<td>Sweden</td>
<td>TWA</td>
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</tr>
</tbody>
</table>

Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Austria MAKs Listed
Belgium TWA Listed
Bulgaria TWA Listed
Czech Republic TWA Listed
Denmark TWA Listed
Estonia TWA Listed
Finland TWA Listed
Greece TWA Listed
Hungary TWA Listed
Ireland TWAs Listed
Latvia TWA Listed
Lithuania TWA Listed
OSHA Final PELs TWAs 15 mg/m³ total
Poland TWA Listed
Portugal TWA Listed
Romania TWA Listed
Spain TWA Listed
Sweden TWA Listed

Ferric oxide red

ACGIH Threshold Limit Value (TWA) 1 mg/m³ TWA
Australia TWA 1 mg/m³
Austria MAKs Listed
Belgium TWA Listed
Bulgaria TWA Listed
Czech Republic TWA Listed
Denmark TWA Listed
Estonia TWA Listed
Finland TWA Listed
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:
Hard-gelatin Capsule

Color:
Light grey, Peach, or Dark orange

Molecular Formula:
Mixture

Molecular Weight:
Mixture

Polymerization:
Will not occur
9. PHYSICAL AND CHEMICAL PROPERTIES

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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 LD 50 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 350 mg/kg

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

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

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

Ferric oxide red  
IARC:  
Group 3

Talc (non-asbestiform)  
IARC:  
Group 3

Titanium dioxide  
IARC:  
Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  
Toxic to aquatic organisms.

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

Oncorhynchus 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.

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

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.

Ethylcellulose
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed

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

Hydroxypropyl methylcellulose
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

Gelatin
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 232-554-6

Talc (non-asbestiform)
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</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>Titanium dioxide</td>
<td>Listed</td>
<td>Listed</td>
<td>238-877-9</td>
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<tr>
<td>Ferric oxide red</td>
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<td>236-675-5</td>
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<tr>
<td>Ferric oxide yellow</td>
<td>Listed</td>
<td>Listed</td>
<td>215-168-2</td>
</tr>
<tr>
<td>Black Iron Oxide</td>
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<td>257-098-5</td>
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<tr>
<td>Ferric oxide yellow</td>
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<td>Listed</td>
<td>215-168-2</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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

R22 - Harmful if swallowed.

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

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a 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