



# MATERIAL SAFETY DATA SHEET

Revision date: 07-Jan-2011

Version: 1.0

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

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

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### Material Name: Venlafaxine Hydrochloride Modified Release Capsules

Trade Name:	EFFEXOR
Chemical Family:	Serotonin Noradrenaline Reuptake Inhibitor
Intended Use:	Pharmaceutical active used as antidepressant

## 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. Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Long Term:

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.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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.

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## 2. HAZARDS IDENTIFICATION

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Venlafaxine hydrochloride	99300-78-4	Not Listed	Xn;R22	30-40
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ethylcellulose	9004-57-3	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*

**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.

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	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.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<b>Venlafaxine hydrochloride</b>	
Pfizer OEL TWA-8 Hr:	250µg/m <sup>3</sup>
<b>Microcrystalline cellulose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
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/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
<b>Talc (non-asbestiform)</b>	
ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup> TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	2.5 mg/m <sup>3</sup> containing no asbestos fibers

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Ferric oxide red

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup> TWA 5 mg/m <sup>3</sup> TWA
Australia TWA	1 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

France OEL - TWA	Listed
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	10 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Ferric oxide yellow

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed

#### Black Iron Oxide

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup> TWA
Australia TWA	1 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

#### 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

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### 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

#### 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)

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### 11. TOXICOLOGICAL INFORMATION

#### Venlafaxine hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Cell Transformation Assay	Mouse	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> 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

<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	38 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD EC50	72 Hours	4.8 mg/L
<i>Oncorhynchus mykiss</i> (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.

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### 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)**



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## 15. REGULATORY INFORMATION

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

### Titanium dioxide

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

### Ferric oxide red

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-168-2

### Ferric oxide yellow

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	257-098-5

### Black Iron Oxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-277-5

## 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**