



SAFETY DATA SHEET

Revision date: 16-May-2016

Version: 3.1

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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
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
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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 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

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Other Hazards 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Venlafaxine hydrochloride	99300-78-4	Not Listed	Acute Tox.4 (H302) Aquatic Acute 2 (H401)	30-40

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Ethylcellulose	9004-57-3	Not Listed	Not Listed	*

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.

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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.

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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)

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	6.0 mg/m ³
	3.0 mg/m ³
Czech Republic OEL - TWA	2.0 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³
Greece OEL - TWA	10 mg/m ³
	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	0.8 mg/m ³
Lithuania OEL - TWA	2 mg/m ³
	1 mg/m ³
Netherlands OEL - TWA	0.25 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m ³
	1.0 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
	10 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³
	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m ³ 4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³ 5 mg/m ³

Ferric oxide red

ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³ 10 mg/m ³
Austria OEL - MAKs	5 mg/m ³ 10 mg/m ³
Belgium OEL - TWA	2 ppm 5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Denmark OEL - TWA	3.5 mg/m ³
Estonia OEL - TWA	3.5 mg/m ³
Finland OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
Hungary OEL - TWA	6 mg/m ³
Ireland OEL - TWAs	5 mg/m ³ 10 mg/m ³ 4 mg/m ³
Lithuania OEL - TWA	3.5 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³ 15 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 mg/m ³
Russia OEL - TWA	6 mg/m ³
Slovakia OEL - TWA	1.5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3.5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m ³ 4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³ 5 mg/m ³

Venlafaxine hydrochloride Pfizer OEL TWA-8 Hr:	250µg/m ³
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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			

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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.

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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))

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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.

Toxicity:

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.

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.

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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	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

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
EU EINECS/ELINCS List	215-168-2

Black Iron Oxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

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15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	215-277-5
Hydroxypropyl methylcellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed
Ethylcellulose	
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	Not Listed
Ferric oxide yellow	
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	257-098-5
Microcrystalline cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9
Venlafaxine hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

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.

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Product Stewardship Hazard Communication

Prepared by:

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