

\*\*\*

Effexor Products

Preparation Date 26-Jul-2007

Revision Date 26-Jan-2010\*\*\*

Revision Number 6\*\*\*

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

<b>Product Name</b>	Effexor Products
<b>Common Name</b>	Not available
<b>Chemical Name</b>	Not applicable
<b>Synonyms</b>	Effexor Tablets, Effexor XR, Effexor Extended-Release Capsules, Effexor Venlafaxine Capsules, Venlafaxine Hydrochloride
<b>Product Use Classification</b>	Pharmaceutical product*** Antidepressant
<b>Supplier</b>	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
<b>Contact E-Mail:</b>	pfizer-MSDS@pfizer.com
<b>Emergency Telephone Number</b>	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

**Appearance** Pharmaceutical tablet or capsule\*\*\*

**Physical State** Solid

**Odor** Not available

#### Potential Physical Hazards

Powders and solids are presumed to be combustible.

#### Potential Health Effects

**Eyes**

Not available

**Skin**

Not available

**Inhalation**

Not available

**Ingestion**

The most common effects may include, hypertension, insomnia, nervousness, headache, sexual dysfunction, vision disturbances, abnormal dreams, loss of appetite, anxiety, weakness, chills, constipation, diarrhea, dizziness, dryness of mouth, heartburn, increased sweating, nausea, burning sensations, runny or stuffy nose, drowsiness, stomach pain, tremor, vomiting, weight loss, yawning, bleeding, serum chemistry effects, memory impairment, unsteadiness. May cause harm to the unborn child.

Please see Patient Package Insert for further information.

**Therapeutic Target Organ(s)**

Central nervous system.

Not listed by OSHA, NTP or IARC.

#### Potential Environmental Effects

See Section 12.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Venlafaxine Hydrochloride	99300-78-4	N/A	25 - 150 mg/tablet or capsule	R61, S13/37/39

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. If skin irritation persists, call a physician.***
<b>Inhalation</b>	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
<b>Ingestion</b>	Immediate medical attention is required

### 5. FIRE-FIGHTING MEASURES

<b>Flammable Properties</b>	Not flammable
<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	Use water spray, foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing Media</b>	Do NOT use water jet.
<b>Fire Fighting</b>	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
<b>Hazardous Combustion Products</b>	Carbon oxides, nitrogen oxides.
<b>Protective Equipment and Precautions for Firefighters</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Safety glasses or goggles when splash potential exists
<b>Environmental Precautions</b>	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
<b>Methods for Containment</b>	Not available
<b>Methods for Cleaning up</b>	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

## 7. HANDLING AND STORAGE

<b>Handling</b>	Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, 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. 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</b>	No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>OEB Statement</b>	The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.***
<b>Venlafaxine Hydrochloride Pfizer OEL TWA-8 Hr:</b>	250 µg/m <sup>3</sup> ***
<b>Engineering Controls</b>	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.***
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Wear safety glasses as minimum protection.***
<b>Skin Protection</b>	Wear impervious protective clothing when handling this compound. Wear impervious gloves as minimum protection.***
<b>Respiratory Protection</b>	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. ***
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Pharmaceutical tablet or capsule***	<b>Physical State</b>	Solid
<b>Color</b>	Various	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>pH</b>	Not available***		
<b>Specific Gravity</b>	Not applicable	<b>Water Solubility</b>	Soluble in water
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not applicable
<b>Partition Coefficient (n-octanol/water)</b>	Not available	<b>Vapor Density</b>	Not applicable
<b>Vapor Pressure</b>	Not applicable		

<b>Boiling Point</b>	Not applicable	<b>Autoignition Temperature</b>	Not applicable
<b>Flash Point</b>	Not applicable	<b>Melting Point</b>	Not available
<b>Flammability Limits in Air</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	
<b>Upper</b> Not applicable	<b>Lower</b> Not applicable		

## 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable at room temperature.
<b>Conditions to Avoid</b>	No data available
<b>Materials to Avoid</b>	No materials to be especially mentioned.
<b>Hazardous Decomposition Products</b>	None under normal use.
<b>Possibility of Hazardous Reactions</b>	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

<b>Venlafaxine Hydrochloride</b>	
<b>LD50 Oral</b>	673 mg/kg male rats 336 mg/kg female rats
<b>Acute Dermal Irritation</b>	Non irritating.
<b>Primary Eye Irritation</b>	Non irritating.
<b>Sensitization</b>	No data available

### Multiple Dose Toxicity

\*\*\*

<b>Venlafaxine Hydrochloride</b>	
<b>No Toxicologic Effect</b>	See Carcinogenicity
<b>Dose/Species/Study Length:</b>	

### Maximum Tolerated Dose (MTD), Oral

<b>Venlafaxine Hydrochloride</b>	
<b>Carcinogenicity</b>	Studies in rats and mice for 24 and 18 months, respectively, have revealed no evidence of an increased risk of tumor development.
<b>Genetic Toxicity</b>	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays. There was a clastogenic response in the <i>in vivo</i> chromosomal aberration assay in rat bone marrow.
<b>Reproductive Toxicity</b>	Studies in rats were found to have no effect on fertility and reproductive performance.
<b>Developmental Toxicity</b>	No teratogenic effects were observed in rats or rabbits. A decrease in pup weight, an increase in still born pups, and an increase in pup deaths during the first 5 days of lactation have also been reported when rats were dosed at pregnancy and continued until weaning.

<b>Venlafaxine Hydrochloride</b>	
<b>Target Organ(s) of Toxicity</b>	No data available

## 12. ECOLOGICAL INFORMATION

**Chemical Fate Information****Venlafaxine Hydrochloride**

<b>Mobility</b>	Soluble in water.
<b>Biodegradability</b>	Not inherently biodegradable.
<b>Stability in Water</b>	Relatively stable.
<b>Bioaccumulation</b>	Bioaccumulation is unlikely.

**Ecotoxicity****Venlafaxine Hydrochloride**

<b>Microorganisms</b>	EC50 > 50 mg/l mg/l***
<b>Algae</b>	EC50/72h/algae = 4.8 mg/l
<b>Daphnia</b>	EC50/48h/daphnia = .? mg/l,
<b>Fish</b>	EC50/96h/rainbow trout ≥ 100 mg/l

**13. DISPOSAL CONSIDERATIONS****Waste Disposal Method**

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****Transport Information**

This material is not regulated for transportation as a hazardous material/dangerous goods.\*\*\*

**15. REGULATORY INFORMATION**

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

**EU Labeling****16. OTHER INFORMATION**

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with Directive 2001/58/EC.
<b>List of References</b>	Product Package Insert
<b>Revision Summary</b>	Changes to Section 8,14***

## Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

**End of MSDS**