

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING****Product Identifier****Material Name: Desvenlafaxine Succinate Extended Release Tablets (Greenstone LLC)**

**Trade Name:** Not established  
**Synonyms:** Desvenlafaxine Succinate Extended Release Tablets  
**Chemical Family:** Serotonin Noradrenaline Reuptake Inhibitor

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against****Intended Use:** Pharmaceutical product used as antidepressant**Details of the Supplier of the Safety Data Sheet**

Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095

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

**2. HAZARDS IDENTIFICATION****Classification of the Substance or Mixture****GHS - Classification**

Acute Oral Toxicity: Category 4  
Acute aquatic toxicity: Category 3

**Label Elements**

**Signal Word:** Warning  
**Hazard Statements:** H302 - Harmful if swallowed  
H402 - Harmful 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  
P273 - Avoid release to the environment  
P501 - Dispose of contents/container in accordance with all local and national regulations

**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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**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	%
Desvenlafaxine Succinate Monohydrate	386750-22-7	Not Listed	Acute Tox.4 (H302) Aquatic Acute 3 (H402)	45
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Iron oxide	1309-37-1	215-168-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	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.

**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

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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 thoroughly after handling. 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.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Desvenlafaxine Succinate Monohydrate

Manufacturer OEL: 350ug/m<sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Australia TWA 10 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Estonia OEL - TWA 10 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
4 mg/m<sup>3</sup>  
Latvia OEL - TWA 2 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 mg/m<sup>3</sup>  
Romania OEL - TWA 10 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>

#### Iron oxide

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

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>  
Sweden OEL - TWAs 5 mg/m<sup>3</sup>

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### Polyethylene glycol

Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>

### Talc (non-asbestiform)

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

### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>

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Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

### 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

#### Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

#### Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

#### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

#### Respiratory protection:

Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Tablets

#### Color:

Various

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water solubility:

30 mg/mL

#### Water Solubility:

No data available

#### pH:

No data available.

#### Melting/Freezing Point (°C):

105

#### Boiling Point (°C):

No data available.

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

#### Venlafaxine hydrochloride

Measured Log P 0.5

#### Polyvinyl alcohol

No data available

#### Titanium dioxide

No data available

#### Iron oxide

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No data available

**Polyethylene glycol**

No data available

**Hydroxypropyl methylcellulose**

No data available

**Magnesium stearate**

No data available

**O-Desmethylvenlafaxine free base**

Predicted 7.0 Log P 2.26

**Microcrystalline cellulose**

No data available

**Desvenlafaxine Succinate Monohydrate**

Measured 6.0 Log P 0.33

**Talc (non-asbestiform)**

No data available

**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:** Keep away from heat and other sources of ignition, including electrostatic discharge.

**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 following information describes the toxicity of a chemically-related material. The toxicities of the two materials can be expected to be similar.

**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

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**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, insomnia, nausea, constipation, vomiting, dry mouth, nervousness, anxiety, tremors, impotence, abnormal dreams, abnormal ejaculation, and sweating. Signs and symptoms associated with non-fatal overdose were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

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

##### **Venlafaxine hydrochloride**

Rat (M) Oral LD50 700 mg/kg  
Rat (F) Oral LD50 350mg/kg

##### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD50 50 mg/kg

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### **Desvenlafaxine Succinate Monohydrate**

Rat IP Minimum Lethal Dose 700 mg/kg

##### **Talc (non-asbestiform)**

Rat Oral LD50 > 1600 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

##### **Venlafaxine hydrochloride**

Eye Irritation (*In vitro*, BCOP) Negative

##### **Polyethylene glycol**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

##### **O-Desmethylvenlafaxine free base**

Skin Corrosivity (*In vitro*, RHE) Negative  
Eye Irritation (*In vitro*, BCOP) Negative  
Skin Sensitization - LLNA Mouse Negative  
Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Negative

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### 11. TOXICOLOGICAL INFORMATION

#### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### Desvenlafaxine Succinate Monohydrate

Skin Corrosivity (*In vitro*, RHE) Negative  
Eye Irritation (*In vitro*, BCOP) Negative  
Skin Sensitization - LLNA Mouse Negative

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Desvenlafaxine Succinate Monohydrate

6 Month(s) Rat Oral 300 mg/kg/day LOAEL None identified  
9 Month(s) Dog Oral 50 mg/kg/day NOAEL No effects at maximum dose

#### 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

##### O-Desmethylvenlafaxine free base

Fertility and Embryonic Development Rat Oral 30 mg/kg/day NOAEL Fertility  
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Developmental toxicity

##### Desvenlafaxine Succinate Monohydrate

Fertility and Embryonic Development Rat Oral 30 mg/kg/day NOAEL Fertility  
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Developmental toxicity  
Embryo / Fetal Development Rabbit Oral 75 mg/kg/day NOAEL No effects at maximum dose

#### 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

##### O-Desmethylvenlafaxine free base

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Micronucleus Mouse Negative  
Forward Mutation Assay Chinese Hamster Ovary (CHO) cells Negative  
*In Vivo* Chromosome Aberration Rat Equivocal

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Venlafaxine hydrochloride

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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 present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

**Polyvinyl alcohol**  
**IARC:** Group 3 (Not Classifiable)

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

**Iron oxide**  
**IARC:** Group 3 (Not Classifiable)

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The information in this section includes the potential hazards of a chemically related material. The toxicities of the two materials can be expected to be similar 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

##### **Desvenlafaxine Succinate Monohydrate**

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 33 mg/L  
*Pimephales promelas* (Fathead Minnow) OECD LC50 96 Hours 9.4 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 72 Hours 32.2 mg/L

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

#### **Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

##### **Desvenlafaxine Succinate Monohydrate**

Activated sludge OECD EC50 > 100 mg/L

#### **Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

##### **Desvenlafaxine Succinate Monohydrate**

*Daphnia magna* (Water Flea) OECD 21 Day(s) NOEC 8.2 mg/L Reproduction  
*Pimephales promelas* (Fathead Minnow) OECD 32 Day(s) NOEC 2.1 mg/L Growth  
*Chironomus riparius* (Sediment-Dwelling Midges) OECD 28 Day(s) NOEC 52 mg/kg

**Persistence and Degradability:** No data available

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**Bio-accumulative Potential:** No data available

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

**Venlafaxine hydrochloride**

Measured Log P 0.5

**O-Desmethylvenlafaxine free base**

Predicted 7.0 Log P 2.26

**Desvenlafaxine Succinate Monohydrate**

Measured 6.0 Log P 0.33

**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**

**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.

**Desvenlafaxine Succinate Monohydrate**

**CERCLA/SARA 313 Emission reporting**

Not Listed

**California Proposition 65**

Not Listed

**EU EINECS/ELINCS List**

Not Listed

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**15. REGULATORY INFORMATION**

**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

**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
EU EINECS/ELINCS List	232-674-9

**Iron oxide**

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

**Magnesium stearate**

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	209-150-3

**Polyvinyl alcohol**

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

**Polyethylene glycol**

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 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

**Talc (non-asbestiform)**

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

## SAFETY DATA SHEET

Material Name: Desvenlafaxine Succinate Extended Release  
Tablets (Greenstone LLC)  
Revision date: 26-Jan-2017

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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

#### Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

### 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.3; H402 - Harmful to aquatic life

**Data Sources:** Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date:** 26-Jan-2017  
Product Stewardship Hazard Communication

**Prepared by:** 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**