

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

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

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

### Material Name: Divalproex Tablets (Greenstone LLC)

Trade Name:	Not applicable
Synonyms:	None
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product for the treatment of, seizures and epilepsy

## 2. HAZARDS IDENTIFICATION

Appearance: Red, Orange, or Pink Tablets  
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.  
Causes eye irritation.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus.

Known Clinical Effects: Adverse effects associated with therapeutic use include nausea, drowsiness, dizziness, vomiting abdominal pain, skin rash. Other, more serious, effects include liver failure, effects on developing fetus, inflammation of the pancreas (pancreatitis).

EU Classification  
EU Indication of danger: Toxic to reproduction: Category 1  
Irritant

EU Hazard Symbols:



EU Risk Phrases:

R61 - May cause harm to the unborn child.  
R36 - Irritating to eyes.  
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 active substance or its intermediates 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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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Divalproex sodium	76584-70-8	Not Listed	Repr. Cat.1,R61; Xi,R36	125, 250, or 500mg***
Silicon dioxide, NF	7631-86-9	231-545-4	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Povidone	9003-39-8	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Film coating	NOT ASSIGNED	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

\*\*\* per tablet/capsule/lozenge/suppository

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

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 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.
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**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**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. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Silicon dioxide, NF

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup> MAK
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(% SiO <sub>2</sub> ) mg/m <sup>3</sup> TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

#### Microcrystalline cellulose

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

#### Talc (non-asbestiform)

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
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

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**Divalproex sodium**  
**Manufacturer OEB:** OEB2 (control exposure to the range of >100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

**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

<b>Physical State:</b>	Tablets	<b>Color:</b>	Red, Orange or Pink
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Water Solubility:</b>	Soluble		

## 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)

#### **Povidone**

Rat Oral LD50 100 g/kg

#### **Microcrystalline cellulose**

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

#### **Silicon dioxide, NF**

Rat Oral LD50 10 g/kg

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

Rat Oral LD50 > 1600 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### Divalproex sodium

Rat Oral LD50 2710 mg/kg  
Mouse Oral LD50 2060 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)

##### Microcrystalline cellulose

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

##### Divalproex sodium

Eye Irritation Rabbit Mild to Moderate  
Eye Irritation Rabbit Severe

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Divalproex sodium

Reproductive & Fertility Rat Oral 350 mg/kg/day NOAEL Negative  
Embryo / Fetal Development Rat Oral 200 mg/kg/day LOAEL Teratogenic  
Embryo / Fetal Development Rabbit Oral 350 mg/kg/day LOAEL Teratogenic  
Embryo / Fetal Development Monkey Oral 200 mg/kg/day LOAEL Teratogenic

**Reproductive & Development Toxicity Comments:** The use of this drug during pregnancy has resulted in birth defects.

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Divalproex sodium

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Dominant Lethal Assay Mouse Negative  
*In Vivo* Cytogenetics Rat Negative

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

##### Divalproex sodium

2 Year(s) Mouse Oral 170 mg/kg/day LOAEL Benign neoplasms  
2 Year(s) Rat Oral 80 mg/kg/day LOAEL Benign neoplasms

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

##### Povidone

IARC: Group 3

##### Silicon dioxide, NF

IARC: Group 3

##### Talc (non-asbestiform)

IARC: Group 3

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

### 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:** Toxic to reproduction: Category 1  
Irritant

**EU Risk Phrases:**  
R61 - May cause harm to the unborn child.  
R36 - Irritating to eyes.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
DANGER  
May damage the unborn child.  
Causes eye irritation.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
D2a very toxic materials  
D1b toxic materials



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### 15. REGULATORY INFORMATION

#### Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4

#### Croscarmellose sodium

Australia (AICS):	Listed
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#### Microcrystalline cellulose

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

#### Povidone

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

#### Hydroxypropyl cellulose

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

#### Talc (non-asbestiform)

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

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R36 - Irritating to eyes.

#### Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

#### Prepared by:

Product Stewardship Hazard Communications  
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**