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

Product Identifier

Material Name: Ethosuximide Oral Solution (Greenstone LLC)

Trade Name: Not applicable
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anticonvulsant anti-epileptic

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

Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 1B

EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 3

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

Label Elements

Signal Word: Danger
Hazard Statements: H341 - Suspected of causing genetic defects
H360D - May damage the unborn child

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards No data available

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	GHS Classification	%
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	Not Listed	*
Ethosuximide	77-67-8	201-048-7	Xn, R22; Repr. Cat.2,R61; Mut. Cat.3,R68	Acute Tox. 4, H302; Repr. 1B, H360D; Muta. 2, H341	5.0
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*
Sodium saccharin	128-44-9	204-886-1	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
FD & C Red No. 40	25956-17-6	247-368-0	Not Listed	Not Listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	Not Listed	*
Sodium dihydrogen citrate	18996-35-5	242-734-6	Not Listed	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	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
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: Not flammable.

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.

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
Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing vapor or mist. 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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ethosuximide

Manufacturer OEL:	2mg/m³

Glycerin, USP

Australia TWA	10 mg/m³
Belgium OEL - TWA	10 mg/m³
Czech Republic OEL - TWA	10 mg/m³
Estonia OEL - TWA	10 mg/m³
Finland OEL - TWA	20 mg/m³
France OEL - TWA	10 mg/m³
Germany (DFG) - MAK	50 mg/m³
Greece OEL - TWA	10 mg/m³
Ireland OEL - TWAs	10 mg/m³
OSHA - Final PELS - TWAs:	15 mg/m³
Poland OEL - TWA	10 mg/m³
Portugal OEL - TWA	10 mg/m³
Spain OEL - TWA	10 mg/m³

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m³
Australia TWA	10 mg/m³
Belgium OEL - TWA	10 mg/m³
Bulgaria OEL - TWA	10.0 mg/m³
Estonia OEL - TWA	10 mg/m³
France OEL - TWA	10 mg/m³
Ireland OEL - TWAs	10 mg/m³
Latvia OEL - TWA	5 mg/m³
Lithuania OEL - TWA	10 mg/m³
OSHA - Final PELS - TWAs:	15 mg/m³
Portugal OEL - TWA	10 mg/m³
Slovakia OEL - TWA	6 mg/m³
Spain OEL - TWA	10 mg/m³

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:	Liquid	**Color:**	Red-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
Solubility: Soluble: Water
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Ethosuximide
No data available
Citric acid, anhydrous
No data available
FD & C Red No. 40
No data available
FD&C yellow No.6 aluminum lake
No data available
Flavor
No data available
Glycerin, USP
No data available
Sodium saccharin
No data available
Sodium dihydrogen citrate
No data available
Sucrose
No data available
Sodium benzoate
No data available
Water, purified
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

Flammablity:
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

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.

10. STABILITY AND REACTIVITY

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:	May be harmful if swallowed. May cause eye irritation (based on components)
Known Clinical Effects:	Effects reported during clinical use included vomiting and diarrhea. Central nervous system effects such as dizziness, headache, insomnia, irritability and weakness have also been reported. Clinical use of this drug has caused decreased blood cell count, increased eosinophils in blood or tissue (eosinophilia), skin rash, Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis). May cause adverse effects on the developing fetus.

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

Ethosuximide
Mouse Oral LD50 1530 mg/kg
Rat Oral LD50 1950mg/kg
Mouse Intravenous LD50 780mg/kg
Mouse Intravenous LD50 1070mg/kg

Citric acid, anhydrous
Rat Oral LD50 3000 mg/kg

Glycerin, USP
Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m^3
Rat Dermal LD 50 > 21.9 g/kg

Sodium saccharin
Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17g/kg
Rat Intraperitoneal LD50 7100mg/kg

Sodium dihydrogen citrate
Rat IP LD50 1348 mg/kg
Mouse IV LD50 49mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Sodium benzoate

11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600mg/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)

Citric acid, anhydrous
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Glycerin, USP
Eye Irritation Rabbit Mild

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

Ethosuximide
3 Month(s) Dog Oral 100 mg/kg/day LOAEL Liver
26 Week(s) Rat Oral 676 mg/kg/day NOAEL None identified
26 Week(s) Dog Oral 100 mg/kg/day NOAEL None identified
26 Week(s) Monkey Oral 200 mg/kg/day NOAEL None identified
1 Year(s) Mouse Oral 136 mg/kg/day LOAEL Liver

Sodium saccharin
36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

Sodium benzoate
10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ethosuximide
Embryo / Fetal Development Rat 60 mg/kg/day LOEL Teratogenic
2 Generation Reproductive Toxicity Rat Oral 0.2 % LOAEL Not Teratogenic, Embryotoxicity
Embryo / Fetal Development Mouse Oral 60 mg/kg/day LOAEL Teratogenic
Prenatal & Postnatal Development Mouse Oral 50 mg/mL NOAEL Embryotoxicity, Reproductive toxicity, Developmental toxicity

Sodium benzoate
Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity,

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

Ethosuximide
In Vitro Cytogenetics Human Negative
In Vivo Micronucleus Mouse Bone Marrow Positive

11. TOXICOLOGICAL INFORMATION

Sucrose
Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

Sodium saccharin
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP
Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 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

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:
Class D, Division 2, Subdivision A

Citric acid, anhydrous

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	201-069-1

Ethosuximide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	201-048-7

FD & C Red No. 40

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	247-368-0

FD&C yellow No.6 aluminum lake

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	239-888-1

Flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Glycerin, USP

15. REGULATORY INFORMATION

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 V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5

Sodium benzoate

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	208-534-8

Sodium dihydrogen citrate

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	242-734-6

Sodium saccharin

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	204-886-1

Sucrose

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 IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Water, purified

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 IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Mutagenic: Category 3
Toxic to Reproduction: Category 2
Xn - Harmful

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R68 - Possible risks of irreversible effects.

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

Revision date: 22-Sep-2015

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