MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Ethosuximide Syrup

Trade Name: Zarontin
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anticonvulsant, anti-epileptic

2. HAZARDS IDENTIFICATION

Appearance: Red-orange liquid
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:
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.
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 3

EU Hazard Symbols:

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

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

2. HAZARDS IDENTIFICATION

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

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

Additional Information: * Proprietary
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

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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not flammable.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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: 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ethosuximide

Pfizer OEL TWA-8 Hr:	2 mg/m^3

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3

Glycerin, USP

ACGIH Threshold Limit Value (TWA)	10 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Czech Republic OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
Finland OEL - TWA	20 mg/m^3
France OEL - TWA	10 mg/m^3
Germany (DFG) - MAK	50 mg/m^3
Greece OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Poland OEL - TWA	10 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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
Molecular Formula: Mixture
Molecular Weight: Mixture

Solubility: Soluble: Water

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.

11. TOXICOLOGICAL INFORMATION

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

Ethosuximide
Mouse Oral LD50 1530 mg/kg
Rat Oral LD50 1950 mg/kg
Mouse Intravenous LD50 780 mg/kg
Mouse Intravenous LD50 1070 mg/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 - 17 g/kg
Rat Intraperitoneal LD50 7100 mg/kg

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

Sucrose
Rat Oral LD50 29.7 g/kg

Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse 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)

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

11. TOXICOLOGICAL INFORMATION

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

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.

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

Glycerin, USP
Oncorhynchus mykiss (Rainbow Trout) LD50 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.

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: T
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.

EU Safety Phrases:
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May damage the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Ethosuximide
Australia (AICS): Present

15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	201-048-7

Sodium dihydrogen citrate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	242-734-6

Citric acid, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

FD & C Red No. 40

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

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	239-888-1

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

Sucrose

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

Sodium saccharin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-886-1

Glycerin, USP

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

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	200-289-5

Water, purified

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 R phrases mentioned in Section 3

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

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 12 - Ecological Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Product Stewardship Hazard Communication
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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet