



MATERIAL SAFETY DATA SHEET

Revision date: 13-Jun-2012

Version: 2.0

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

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Material Name: Ethosuximide Capsules

Trade Name:	Zarontin
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as anticonvulsant

2. HAZARDS IDENTIFICATION

Appearance: Orange capsules
Signal Word: DANGER

Statement of Hazard: May be harmful if swallowed.
May damage the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:

Short Term: May be harmful if swallowed. (based on animal data) .
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: Harmful
Toxic to Reproduction: Category 2
Mutagenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:

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

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2. HAZARDS IDENTIFICATION

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	%
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Ethosuximide	77-67-8	201-048-7	Xn, R22; Repr. Cat.2,R61; Mut. Cat.3,R68	250mg ***

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
FD & C Red No. 3 (E 127)	16423-68-0	240-474-8	Not Listed	*
Polyethylene glycol 400	25322-68-3	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*
Sorbitol	6706-59-8	Not Listed	Not Listed	*
D & C yellow No. 10	8004-92-0	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.

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.

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

Fire / Explosion Hazards: Not applicable

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 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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.

Glycerin, USP

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

Ethosuximide

Pfizer OEL TWA-8 Hr:	2 mg/m ³
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Polyethylene glycol 400

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ inhalable fraction
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 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:	Capsule	Color:	Orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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

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

D & C yellow No. 10

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 2000 mg/kg

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Rat Oral LD50 1840 mg/kg

Mouse Oral LD50 1264 mg/kg

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

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)

Glycerin, USP

Eye Irritation Rabbit Mild

Polyethylene glycol 400

Eye Irritation Rabbit Mild

Skin 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

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

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

Ethosuximide

In Vitro Cytogenetics Human Negative

In Vivo Micronucleus Mouse Bone Marrow Positive

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

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. 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: Harmful
Toxic to Reproduction: Category 2
Mutagenic: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER

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15. REGULATORY INFORMATION

May be harmful if swallowed.
May damage the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



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

EU EINECS/ELINCS List

200-289-5

FD & C Red No. 3 (E 127)

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

240-474-8

Ethosuximide

Australia (AICS):

Present

Standard for the Uniform Scheduling for Drugs and Poisons:

Schedule 4

EU EINECS/ELINCS List

201-048-7

Polyethylene glycol 400

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

Gelatin

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

232-554-6

D & C yellow No. 10

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

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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. Safety data sheets for individual ingredients.
Publicly available toxicity information.

Reasons for Revision: Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.
Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations.
Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated
Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal
Protection.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet