



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

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### Material Name: Ethosuximide Capsules

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

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Glycerin, USP	56-81-5	200-289-5	*
Ethosuximide	77-67-8	201-048-7	250 ***

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

### Additional Information:

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

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Orange capsules  
**Signal Word:** WARNING

**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).

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**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.

**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.

### 4. FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove contaminated clothing and flush exposed area with water. Obtain medical assistance if irritation occurs, which may be delayed.

**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.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide and oxides of nitrogen.

**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.

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**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.

**Storage Conditions:** Store in a cool, dry place away from direct sunlight.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Glycerin, USP

OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA	total
	= 5 mg/m <sup>3</sup> TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	
Australia TWA	= 10 mg/m <sup>3</sup> TWA	

#### Ethosuximide

Pfizer OEL TWA-8 Hr: 2 mg/m<sup>3</sup>  
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. If dust is present, a laboratory fume hood, local exhaust ventilation or an appropriate respirator should be used. The specific type used will be determined by air concentrations present. Follow local regulations for respirator use in the workplace.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Capsule	<b>Color:</b>	Orange
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None known

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

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**Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

## 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)

#### **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<sup>3</sup>  
Rat Dermal LD 50 >21.9 g/kg

#### **D & C yellow No. 10**

Rat Oral LD50 2000 mg/kg

#### **FD & C Red No. 3 (E 127)**

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 LOEL 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 LOEL 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 % LOEL Not Teratogenic, Embryotoxicity  
Embryo / Fetal Development Mouse Oral 60 mg/kg/day LOEL Teratogenic



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

## OSHA Label:

WARNING

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



### Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

### Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

### FD & C Red No. 3 (E 127)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	240-474-8

### Ethosuximide

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	201-048-7

### Polyethylene glycol 400

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

### D & C yellow No. 10

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

## 16. OTHER 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.

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**Prepared by:**

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**