



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.2

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

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Material Name: Ethosuximide Syrup

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ethosuximide	77-67-8	201-048-7	5.0
Citric acid, anhydrous	77-92-9	201-069-1	*
Sodium saccharin	128-44-9	204-886-1	*
Glycerin, USP	56-81-5	200-289-5	*

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

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Viscous red/orange liquid
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 cause eye irritation (based on components) .

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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: 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.

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 wash the affected area with soap and water. Seek medical attention if unusual symptoms occur.

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 nitrogen oxide.

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 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.

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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. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Glycerin, USP

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

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: None required under normal conditions of use. 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:	Viscous liquid	Color:	Red-orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		

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 oxides of nitrogen.

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/m³
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

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1 Year(s) Mouse Oral 136 mg/kg/day LOEL Liver

Sodium saccharin

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

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOEL 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 % LOEL Not Teratogenic, Embryotoxicity
Embryo / Fetal Development Mouse Oral 60 mg/kg/day LOEL Teratogenic
Prenatal & Postnatal Development Mouse Oral 50 mg/mL NOEL 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

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

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) LC-50 96 Hours 50 mg/L
Daphnia Magna (Water Flea) EC-50 24 Hours >500 mg/L

Aquatic Toxicity Comments:

A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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 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



Ethosuximide

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

Sodium dihydrogen citrate

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

Citric acid, anhydrous

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1
FD & C Red No. 40	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	247-368-0
FD&C yellow No.6 aluminum lake	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	239-888-1
Sodium benzoate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	208-534-8
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
Sucrose	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9
Sodium saccharin	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1
Glycerin, USP	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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