



MATERIAL SAFETY DATA SHEET

Revision date: 18-Jan-2007

Version: 1.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Phenytoin Oral Suspension (100mg/5ml; 125mg/5ml)

Trade Name: Dilantin®; Dilantin-125®; Epanutin®; Epamin®; Epelin®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for seizures and epilepsy.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Glycerin, USP	56-81-5	200-289-5	*
Phenytoin	57-41-0	200-328-6	2-2.5
Ethyl alcohol (ethanol)	64-17-5	200-578-6	< 1
Sucrose	57-50-1	200-334-9	*

Ingredient	CAS Number	EU EINECS List	%
Citric acid, anhydrous	77-92-9	201-069-1	*
Concentrated orange oil	8008-57-9	Not listed	*
Imitation banana oil	NOT ASSIGNED	Not listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
Magnesium aluminum silicate	1327-43-1	215-478-8	*
Polysorbate 40	9005-66-7	Not listed	*
Purified water	7732-18-5	231-791-2	*
Sodium benzoate	532-32-1	208-534-8	*
Vanillin	121-33-5	204-465-2	*

Additional Information:

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

3. HAZARDS IDENTIFICATION

Appearance: Orange suspension
Signal Word: WARNING

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Statement of Hazard: Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging the unborn child.
May cause damage to central nervous system through prolonged or repeated exposure.

Additional Hazard Information:

Short Term:

Long Term:

May cause eye irritation (based on components) .
Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs, gastrointestinal system and liver.

Known Clinical Effects:

The most common adverse effects observed with clinical use of phenytoin are lack of appetite, headache, dizziness, transient nervousness, ataxia, slurred speech, decreased coordination, mental confusion, insomnia, and GI disturbances (nausea, vomiting, and constipation). IV administration has been associated with hypotension and CNS depression. Mild hypersensitivity reactions (skin rashes) are common. Effects on blood-forming organs and the liver have occurred rarely. Other less common effects include swollen lymph nodes, sore mouth and symptoms of dependence/withdrawal. There is an unconfirmed association between the use of anticonvulsants during pregnancy and an increased risk of birth defects. This material has been shown to be secreted in low concentrations in human breast milk.

EU Indication of danger:

Carcinogenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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 clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: No data available

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Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards: No data available

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: Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.

Storage Conditions: Protect from freezing. Protect from light.

Storage Temperature: Store at controlled room temperature 20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Phenytoin

Pfizer OEL TWA-8 Hr: 0.4 mg/m³

Ethyl alcohol (ethanol)

OSHA - Final PELs - TWAs: = 1000 ppm TWA
= 1900 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1000 ppm TWA
= 1880 mg/m³ TWA

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

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

Analytical Method: Analytical method available for Phenytoin. Contact Pfizer Inc for further information.

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

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Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Wear protective clothing when working with large quantities.
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:	Suspension	Color:	Orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light and freezing .
Incompatible Materials: None identified
Polymerization: Will not occur

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)

Sodium benzoate

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

Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060 mg/kg
Rat Inhalation LC50 10h 20,000 ppm

Vanillin

Rat Oral LD 50 1580 mg/kg

FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg

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Mouse Oral LD50 > 6,000 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

Phenytoin

Mouse Oral LD50 150 mg/kg

Rat Oral LD50 1635 mg/kg

Rat Intravenous LD 50 96 mg/kg

Rat IM LD 50 >337 mg/kg

Rabbit Oral LD 50 >3000 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)

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe

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)

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

Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOEL Liver, Kidney, Ureter, Bladder

Phenytoin

2 Week(s) Rat Oral <3125 ppm/day NOEL Bone marrow

2 Week(s) Mouse Oral <125 ppm/day NOEL Central Nervous System

13 Week(s) Rat Oral 300 ppm/day NOEL None identified

13 Week(s) Mouse Oral 150 ppm/day NOEL Blood forming organs, Gastrointestinal system, Liver

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

Sodium benzoate

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

Phenytoin

Embryo / Fetal Development Mouse Oral 75 mg/kg/day NOEL Maternal toxicity, Fetotoxicity, Teratogenic

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Embryo / Fetal Development	Mouse	Oral	45 mg/kg/day	NOEL	Teratogenic
Embryo / Fetal Development	Rabbit	Oral	50 mg/kg/day	NOEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Monkey	Oral	10 mg/kg/day	NOEL	Fetotoxicity, Teratogenic
Embryo / Fetal Development	Mouse	Subcutaneous	<12.5 mg/kg/day	NOEL	Maternal Toxicity, Fetotoxicity, Teratogenic

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

Phenytoin

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Sister Chromatid Exchange	Human Lymphocytes	Positive
<i>In Vivo</i> Mitotic Spindle Assay	Human Lymphocytes	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Phenytoin

2 Year(s)	Male Rat	Oral, in feed	50 mg/kg/day	NOEL	Benign neoplasms, Skin
2 Year(s)	Mouse	Oral, in feed	25 mg/kg/day	NOEL	Benign tumors, Liver
2 Year(s)	Female Mouse	Oral, in feed	60 ppm	LOAEL	Liver, neoplasms
2 Year(s)	Female Rat	Oral, in feed	240 ppm	NOAEL	Not carcinogenic

Carcinogen Status: See below

FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3

Phenytoin

IARC: Group 2B
NTP: Reasonably Anticipated To Be A Carcinogen
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data, below:

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

Ethyl alcohol (ethanol)

Rainbow Trout LC50/96h 12,900-15,300 mg/L

Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LD50	96 Hours	50 mg/L
<i>Daphnia Magna</i> (Water Flea)	EC50	24 Hours	>500 mg/L

Phenytoin

<i>Hyallela azteca</i> (Freshwater Amphipod)	OPPTS	LC50	96 Hours	18 mg/L
<i>Daphnia Magna</i> (Water Flea)	TAD	EC50	48 Hours	>39 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	OPPTS	LC50	96 Hours	>23 mg/L

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Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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: Xn
EU Indication of danger: Carcinogenic: Category 3

EU Risk Phrases: R40 - Limited evidence of a carcinogenic effect

EU Safety Phrases: S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging the unborn child.
May cause damage to central nervous system through prolonged or repeated exposure.

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
EU EINECS List	200-289-5

Citric acid, anhydrous

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<p>Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List</p>	<p>Present Present 201-069-1</p>
<p>Concentrated orange oil Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:</p>	<p>Present Present Schedule 5</p>
<p>Phenytoin CERCLA/SARA 313 Emission reporting California Proposition 65</p> <p>Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS List</p>	<p>= 0.1 % de minimis concentration carcinogen, initial date 1/1/88 developmental toxicity, initial date 7/1/87</p> <p>Present Schedule 4</p> <p>200-328-6</p>
<p>Ethyl alcohol (ethanol) California Proposition 65</p> <p>Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List</p>	<p>developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)</p> <p>Present Present 200-578-6</p>
<p>Sucrose Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List</p>	<p>Present Present 200-334-9</p>
<p>Carboxymethylcellulose sodium Inventory - United States TSCA - Sect. 8(b) Australia (AICS):</p>	<p>XU Present</p>
<p>FD&C Yellow No. 6; (Sunset yellow) Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List</p>	<p>Present Present 220-491-7</p>
<p>Magnesium aluminum silicate Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List</p>	<p>Present Present 215-478-8</p>
<p>Polysorbate 40 Inventory - United States TSCA - Sect. 8(b) Australia (AICS):</p>	<p>XU Present</p>
<p>Purified water Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List</p>	<p>Present Present 231-791-2</p>
<p>Sodium benzoate Inventory - United States TSCA - Sect. 8(b)</p>	<p>Present</p>

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Australia (AICS):	Present
EU EINECS List	208-534-8

Vanillin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-465-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet