



MATERIAL SAFETY DATA SHEET

Revision date: 28-Jan-2011

Version: 2.0

Page 1 of 11

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

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

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. HAZARDS IDENTIFICATION

Appearance: Orange suspension
Signal Word: DANGER

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

Additional Hazard Information:

Short Term: May cause eye irritation (based on components) .
Long Term: 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 Classification

EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction: Category 2

EU Hazard Symbols:



EU Risk Phrases:

SUSPENSION

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 2 of 11

Version: 2.0

2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC):

R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.
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 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.

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	*
Phenytoin	57-41-0	200-328-6	Carc.Cat.3;R40 Repr.Cat.2;R61 Xn;R22	2-2.5
Sucrose	57-50-1	200-334-9	Not Listed	*
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F;R11	< 1

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

SUSPENSION

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 3 of 11

Version: 2.0

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: Fine particles (such as dust and mists) may fuel fires/explosions.

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. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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: Protect from freezing. Protect from light. 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 TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 4 of 11

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	50 mg/m ³ MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m ³ total 5 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Phenytoin

Pfizer OEL TWA-8 Hr:	400 µg/m ³
----------------------	-----------------------

Magnesium aluminum silicate

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed

Sucrose

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

Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (TWA)	1000 ppm TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	1000 ppm 1880 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m ³
Germany (DFG) - MAK	500 ppm MAK 960 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 5 of 11

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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. 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:	Suspension	Color:	Orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

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.

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

SUSPENSION

MATERIAL SAFETY DATA SHEET

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

Revision date: 28-Jan-2011

Page 6 of 11

Version: 2.0

11. TOXICOLOGICAL INFORMATION

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
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
Skin Irritation Rabbit Mild

Citric acid, anhydrous

Eye Irritation Rabbit Severe

MATERIAL SAFETY DATA SHEET

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

Revision date: 28-Jan-2011

Page 7 of 11

Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

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)

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Phenytoin

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

In Vitro Chromosome Aberration Human Lymphocytes Negative

In Vivo Sister Chromatid Exchange Human Lymphocytes Positive

In Vivo 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 LOEL Liver, neoplasms

2 Year(s) Female Rat Oral, in feed 240 ppm NOEL Not carcinogenic

SUSPENSION

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 8 of 11

Version: 2.0

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: See below

Ethyl alcohol (ethanol)

IARC: Group 1
NTP: Listed
OSHA: Present

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

IARC: Group 3

Phenytoin

IARC: Group 2B
NTP: Listed
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)

Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Glycerin, USP

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

Phenytoin

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

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 9 of 11

Version: 2.0

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction: Category 2

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.

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

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

Canada - WHMIS: Classifications

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



Glycerin, USP

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

Concentrated orange oil

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5

Carboxymethylcellulose sodium

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

Polysorbate 40

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

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (100mg/5ml;
125mg/5ml)
Revision date: 28-Jan-2011

Page 10 of 11

Version: 2.0

15. REGULATORY INFORMATION

Australia (AICS):	Listed
Vanillin	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	204-465-2
Phenytoin	
CERCLA/SARA 313 Emission reporting California Proposition 65	0.1% de minimis concentration carcinogen, initial date 1/1/88 developmental toxicity, initial date 7/1/87
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-328-6
Citric acid, anhydrous	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-069-1
Sodium benzoate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	208-534-8
Magnesium aluminum silicate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	215-478-8
FD&C Yellow No. 6; (Sunset yellow)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	220-491-7
Purified water	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Sucrose	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9
Ethyl alcohol (ethanol)	

MATERIAL SAFETY DATA SHEET

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

Revision date: 28-Jan-2011

Page 11 of 11

Version: 2.0

15. REGULATORY INFORMATION

California Proposition 65	carcinogen, initial date 7/1/88 (when associated with alcohol abuse) developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-578-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.

R22 - Harmful if swallowed.

R40 - Limited evidence of a carcinogenic effect

R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage.

Prepared by: Product Stewardship Hazard Communications
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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet