



MATERIAL SAFETY DATA SHEET

Revision date: 02-Oct-2007

Version: 2.0

Page 1 of 8

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

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

Material Name: Phenytoin Sodium Capsules (100 mg)

Trade Name:	DILANTIN; EPANUTIN; EPAMIN
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used for seizures and epilepsy.

2. HAZARDS IDENTIFICATION

Appearance: Orange and white capsules
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging the unborn child.

Additional Hazard Information:
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 Indication of danger: Harmful
Carcinogenic: Category 3
Toxic to Reproduction; Category 3

EU Hazard Symbols:



EU Risk Phrases:

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 2 of 8
Version: 2.0

Australian Hazard Classification (NOHSC):

R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of 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	Classification	%
Phenytoin Sodium	630-93-3	211-148-2	Carc.Cat3;R40 Repr.Cat.3;R63 Xn;R22 R52	44
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9 EEC No. 456-230-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Confectioner's sugar	MIXTURE	Not listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not listed	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.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 3 of 8
Version: 2.0

Hazardous Combustion Products: No data available

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.

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Phenytoin Sodium

Pfizer OEL TWA-8 Hr: 400 µg/m³

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA	
Belgium OEL - TWA	= 10 mg/m ³ TWA	
Ireland OEL - TWAs	= 10 mg/m ³ TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m ³ IPRV	
Portugal OEL - TWA	= 10 mg/m ³ TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m ³ VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m ³ LLV	

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA	particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes	Listed	

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 4 of 8
Version: 2.0

Australia TWA	= 2.5 mg/m ³ TWA	containing no asbestos fibers
Austria OEL - MAKs	= 2 mg/m ³ MAK	asbestos-free fibers
Belgium OEL - TWA	= 2 mg/m ³ TWA	
Bulgaria OEL - TWA	= 1.0 f/cm ³ TWA	containing <2% uncombined crystalline silicon dioxide
	= 3.0 mg/m ³ TWA	
	= 6.0 mg/m ³ TWA	
Czech Republic OEL - TWA	= 10 mg/m ³ TWA	
	= 2.0 mg/m ³ TWA	
Denmark OEL - TWA	= 0.3 fiber/cm ³ TWA	
Estonia OEL - TWA	= 0.5 mg/m ³ TWA	
	= 1 mg/m ³ TWA	
Finland OEL - TWA	= 0.5 fibers/cm ³ TWA	
	= 5 mg/m ³ TWA	
Greece OEL - TWA	= 10 mg/m ³ TWA	
	= 2 mg/m ³ TWA	
Hungary OEL - TWA	= 2 mg/m ³ TWA	
Ireland OEL - TWAs	= 0.8 mg/m ³ TWA	
	= 10 mg/m ³ TWA	
Netherlands OEL - TWA	= 1 mg/m ³ MAC	
OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA	
Poland OEL - TWA	= 1.0 mg/m ³ NDS	
	= 4.0 mg/m ³ NDS	
Portugal OEL - TWA	= 2 mg/m ³ TWA	
Romania OEL - TWA	= 2 mg/m ³ TWA	
Slovakia OEL - TWA	= 10 mg/m ³ TWA	
	= 2 mg/m ³ TWA	
Slovenia OEL - TWA	= 2 mg/m ³ TWA	
Spain OEL - TWA	= 2 mg/m ³ VLA-ED	this value is for the particulated matter that is free from asbestos and contains less than 1% of crystalline silica
	= 1 mg/m ³ LLV	
Sweden OEL - TWAs	= 2 mg/m ³ LLV	

The exposure limit(s) listed for solid components are only relevant if dust 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.

Personal Protective Equipment:

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 and White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 5 of 8
Version: 2.0

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: No data available
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. The information in this section describes the hazards of various forms of the active ingredient.

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

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

Phenytoin Sodium

Mouse	Oral	LD50	165 mg/kg
Rat	Oral	LD50	1530 mg/kg
Rat	IV	LD50	90 mg/kg
Mouse	IV	LD 50	98 mg/kg

Lactose Monohydrate

Rat	Oral	LD 50	29700 mg/kg
-----	------	-------	-------------

Talc (non-asbestiform)

Rat	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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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

Magnesium Stearate

13 Week(s)	Rat	Oral	1092 g/kg	LOAEL	Liver
------------	-----	------	-----------	-------	-------

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

Phenytoin

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 6 of 8
Version: 2.0

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)

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

Phenytoin

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

Phenytoin Sodium

IARC:	Group 2B
OSHA:	Present

Talc (non-asbestiform)

IARC:	Group 3
-------	---------

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)

Phenytoin

<i>Hyalella 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

MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 7 of 8
Version: 2.0

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. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol:

Xn

EU Indication of danger:

Harmful

Carcinogenic: Category 3

Toxic to Reproduction; Category 3

EU Risk Phrases:

R22 - Harmful if swallowed.

R40 - Limited evidence of a carcinogenic effect

R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:

S22 - Do not breathe dust.

S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

WARNING

Harmful if swallowed.

Suspected of causing cancer.

Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a very toxic materials



MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Sodium Capsules (100 mg)
Revision date: 02-Oct-2007

Page 8 of 8
Version: 2.0

Phenytoin Sodium

California Proposition 65	carcinogen, initial date 1/1/88
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	211-148-2

Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9 EEC No. 456-230-0

Lactose Monohydrate

Australia (AICS):	Present
-------------------	---------

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R40 - Limited evidence of a carcinogenic effect

R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 15 - Regulatory 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