MATERIAL SAFETY DATA SHEET

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

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

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

Material Name: Phenytoin Tablets

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Phenytoin	57-41-0	200-328-6	9
Magnesium Stearate	557-04-0	209-150-3	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*

Ingredient	CAS Number	EU EINECS List	%
Confectioner's sugar	MIXTURE	Not listed	*
D&C Yellow #10, aluminum lake	Not available	Not listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	*
Lactose	63-42-3	200-559-2	*
Purified water	7732-18-5	231-791-2	###
Sodium saccharin USP	128-44-9	204-886-1	*
Spearmint Flavor, natural	NOT ASSIGNED	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Yellow chewable tablet
Signal Word: WARNING

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:
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: Carcinogenic: Category 3
Toxic to Reproduction; Category 3

EU Hazard Symbols:

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child.

Australian Hazard Classification (NOHSC): 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.

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

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: 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).

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

Storage Temperature: Store below 25°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Phenytoin

Pfizer OEL TWA-8 Hr:	0.4 mg/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	

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA	
ACGIH Threshold Limit Value (TWA)	= 2 mg/m^3 TWA	
Australia TWA	= 2.5 mg/m^3 TWA	containing no asbestos fibers

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.

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:	chewable tablet	**Color:**	Yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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)

Lactose
Rat Oral LD50 > 10 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

Sodium saccharin USP
Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/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
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) *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 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

Sodium saccharin USP
IARC: Group 3

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
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

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
Toxic to Reproduction; Category 3

EU Risk Phrases:
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.
May cause damage to central nervous system through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

Phenytoin

CERCLA/SARA 313 Emission reporting	= 0.1 % de minimis concentration
California Proposition 65	carcinogen, initial date 1/1/88 developmental toxicity, initial date 7/1/87
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-328-6

FD&C yellow No.6 aluminum lake

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

EU EINECS List	239-888-1

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Magnesium Stearate

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

Purified water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Sodium saccharin USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

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