MATERIAL SAFETY DATA SHEET

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

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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.
May damage 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 2

EU Hazard Symbols:

T

EU Risk Phrases:

2. HAZARDS IDENTIFICATION

R22 - Harmful if swallowed.
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Phenytoin Sodium	630-93-3	211-148-2	Carc.Cat3;R40 Repr.Cat.2;R61 Xn;R22	44
Magnesium Stearate	557-04-0	209-150-3	OEL	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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.

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). 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: 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/m^3

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3 TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	2.5 mg/m^3 containing no asbestos fibers

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
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 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: Capsule
Color: Orange and White
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. 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
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

11. TOXICOLOGICAL INFORMATION

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

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) 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: Listed
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
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.

15. REGULATORY INFORMATION

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

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.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of causing cancer.
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

15. REGULATORY INFORMATION

Phenytoin Sodium

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

Magnesium Stearate

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

Talc (non-asbestiform)

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

Lactose Monohydrate

Australia (AICS):	Listed

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information.

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