



# SAFETY DATA SHEET

Revision date: 23-Apr-2015

Version: 2.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Phenytoin Sodium Capsules (100 and 300mg)

**Trade Name:** Dilantin; Epanutin; Epamin

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used for seizures and epilepsy.

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

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:**

**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 2

#### EU Classification:

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.

R52 - Harmful to aquatic organisms.

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H302 - Harmful if swallowed

H351 - Suspected of causing cancer

H360D - May damage the unborn child

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### Precautionary Statements:

P202 - Do not handle until all safety precautions have been read and understood  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P281 - Use personal protective equipment as required  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards  
Australian Hazard Classification (NOHSC):

No data available  
Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Phenytoin Sodium	630-93-3	211-148-2	Carc.Cat3;R40 Repr.Cat.2;R61 Xn;R22	Acute Tox. 4 (H302) Carc. 2 (H351) Repr. 1B (H360D)	80
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Silica colloidal, Ph. Eur.	112945-52-5	Not Listed	Not Listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	Not Listed	*

### Additional Information:

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

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### 4. FIRST AID MEASURES

#### Description of 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.

#### Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** No data available
- Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

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

#### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** No data available
- Fire / Explosion Hazards:** No data available

#### Advice for Fire-Fighters

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

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

- 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.
- 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

#### Precautions for Safe Handling

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### 7. HANDLING AND STORAGE

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 thoroughly after handling. 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.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Phenytoin Sodium

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

#### Silica colloidal, Ph. Eur.

Austria OEL - MAKs 4 mg/m<sup>3</sup>

#### Magnesium Stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Analytical Method:

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

#### Exposure Controls

##### 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:

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:

Green

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

No data available.

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)

**Phenytoin**

Predicted 7.4 Log D 2.47

**Phenytoin Sodium**

No data available

**Magnesium Stearate**

No data available

**Lactose**

No data available

**Silica colloidal, Ph. Eur.**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** No data available

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**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.

**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.

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### 11. TOXICOLOGICAL INFORMATION

**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.

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

##### Phenytoin

Mouse	Oral	LD50	150 mg/kg
Rat	Oral	LD50	1635mg/kg
Rat	Intravenous	LD 50	96mg/kg
Rat	IM	LD 50	>337mg/kg
Rabbit	Oral	LD 50	>3000mg/kg

##### Phenytoin Sodium

Mouse	Oral	LD50	165 mg/kg
Rat	Oral	LD50	1530mg/kg
Rat	IV	LD50	90mg/kg
Mouse	IV	LD 50	98mg/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
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#### 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)	<i>Salmonella</i>	Negative
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### 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

#### **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 (Possibly Carcinogenic to Humans)  
**NTP:** Reasonably Anticipated To Be A Human Carcinogen

##### **Phenytoin Sodium**

**IARC:** Group 2B (Possibly Carcinogenic to Humans)  
**NTP:** Reasonably Anticipated To Be A Human Carcinogen

##### **Silica colloidal, Ph. Eur.**

**IARC:** Group 3 (Not Classifiable)

### 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:

#### **Toxicity:**

#### **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.

**Persistence and Degradability:** No data available

#### **Bio-accumulative Potential:**

##### **Partition Coefficient: (Method, pH, Endpoint, Value)**

##### **Phenytoin**

Predicted 7.4 Log D 2.47

**Mobility in Soil:** No data available

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### 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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

WHMIS hazard class:  
D2a very toxic materials



#### Phenytoin Sodium

CERCLA/SARA 313 Emission reporting	Not Listed
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

#### Silica colloidal, Ph. Eur.

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Lactose



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### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2

#### Magnesium Stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Carcinogenic: Category 3  
Toxic to Reproduction: Category 2  
Xn - Harmful

R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect  
R61 - May cause harm to the unborn child.

**Data Sources:** Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

**Revision date:** 23-Apr-2015  
Product Stewardship Hazard Communication

**Prepared by:** 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**