SAFETY DATA SHEET

Revision date: 14-Apr-2015
Version: 3.0
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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Phenytoin Tablets
Trade Name: Dilantin®; Epanutin®; Infatabs®
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
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1B
Carcinogenicity: Category 2

EU Classification:
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.

Label Elements

Signal Word: Danger
Hazard Statements:
H360D - May damage the unborn child
H351 - Suspected of causing cancer

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
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
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Phenytoin</td>
<td>57-41-0</td>
<td>200-328-6</td>
<td>Carc. Cat. 3; R40</td>
<td>Acute Tox 4 (H302)</td>
<td>9</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Rep. Cat. 2; R61</td>
<td>Carc. 2 (H351)</td>
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</tr>
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<td></td>
<td></td>
<td>Xn; R22</td>
<td>Repr. 1B (H360D)</td>
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<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

**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

### 4. FIRST AID MEASURES

**Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

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: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

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.

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**

- **Pfizer OEL TWA-8 Hr:** 400 µg/m³

**Magnesium Stearate**

- **ACGIH Threshold Limit Value (TWA):** 10 mg/m³
- **Lithuania OEL - TWA:** 5 mg/m³
- **Sweden OEL - TWAs:** 5 mg/m³

**Talc (non-asbestiform)**

- **ACGIH Threshold Limit Value (TWA):** 2 mg/m³
- **Australia TWA:** 2.5 mg/m³
- **Austria OEL - MAKs:** 2 mg/m³
- **Belgium OEL - TWA:** 2 mg/m³
- **Bulgaria OEL - TWA:** 1.0 fiber/cm³
- **Czech Republic OEL - TWA:** 2.0 mg/m³
- **Denmark OEL - TWA:** 0.3 fiber/cm³
- **Finland OEL - TWA:** 0.5 fiber/cm³
- **Greece OEL - TWA:** 10 mg/m³
  - 2 mg/m³
  - 6.0 mg/m³
  - 3.0 mg/m³
- **Hungary OEL - TWA:** 2 mg/m³
- **Ireland OEL - TWAs:** 10 mg/m³
  - 0.8 mg/m³
- **Lithuania OEL - TWA:** 2 mg/m³
  - 1 mg/m³
- **Netherlands OEL - TWA:** 0.25 mg/m³
- **OSHA - Final PELs - Table Z-3 Mineral D:** 20 mppcf
- **Poland OEL - TWA:** 4.0 mg/m³
  - 1.0 mg/m³
- **Portugal OEL - TWA:** 2 mg/m³
- **Romania OEL - TWA:** 2 mg/m³
- **Slovakia OEL - TWA:** 2 mg/m³
  - 10 mg/m³
- **Slovenia OEL - TWA:** 2 mg/m³
- **Spain OEL - TWA:** 2 mg/m³
- **Sweden OEL - TWAs:** 2 mg/m³
  - 1 mg/m³
- **Switzerland OEL -TWAs:** 2 mg/m³

**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).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Chewable tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| 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. |
| Partition Coefficient: (Method, pH, Endpoint, Value) | Predicted 7.4 Log D 2.47 |
| Lactose | No data available |
| Phenytoin | No data available |
| Confectioner’s sugar | No data available |
| D&C Yellow #10, aluminum lake | No data available |
| FD&C yellow No.6 aluminum lake | No data available |
| Sodium saccharin USP | No data available |
| Spearmint Flavor, natural | No data available |
| Talc (non-asbestiform) | No data available |
| Magnesium Stearate | No data available |
| Purified water | 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: | No data available |
| 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 |
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: Fine particles (such as dust and mists) may fuel fires/explosions.
  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.
Short Term: Active ingredient may be harmful if swallowed.
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.

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

Sodium saccharin USP
Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17g/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
# 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Duration</th>
<th>End Point</th>
<th>Effect(s)</th>
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<tbody>
<tr>
<td>Reproduction &amp; Developmental Toxicity</td>
<td>Mouse</td>
<td>Oral</td>
<td>75 mg/kg/day</td>
<td>NOEL</td>
<td>Maternal toxicity, Fetotoxicity, Teratogenic</td>
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<td>Mouse</td>
<td>Oral</td>
<td>45 mg/kg/day</td>
<td>NOEL</td>
<td>Teratogenic</td>
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<tr>
<td></td>
<td>Rabbit</td>
<td>Oral</td>
<td>50 mg/kg/day</td>
<td>NOEL</td>
<td>Fetotoxicity, Teratogenic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monkey</td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>NOEL</td>
<td>Fetotoxicity, Teratogenic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>&lt;12.5 mg/kg/day</td>
<td>NOEL</td>
<td>Maternal Toxicity, Fetotoxicity, Teratogenic</td>
<td></td>
</tr>
</tbody>
</table>

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

- **Sodium saccharin USP**
  - IARC: Group 3 (Not Classifiable)

- **Talc (non-asbestiform)**
  - 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

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
### 15. REGULATORY INFORMATION

**Phenytoin**
- **CERCLA/SARA 313 Emission reporting**: 0.1 %
- **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/ELINCS List**: 200-328-6

**Confectioner’s sugar**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed

**D&C Yellow #10, aluminum lake**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed

**Lactose**
- **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

**Purified water**
- **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**: 231-791-2

**Spearmint Flavor, natural**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance/Ingredient</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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</thead>
<tbody>
<tr>
<td>Talc (non-asbestiform)</td>
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</tr>
<tr>
<td>FD&amp;C yellow No.6 aluminum lake</td>
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<tr>
<td>Sodium saccharin USP</td>
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<td>239-888-1</td>
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</tbody>
</table>

### 16. OTHER INFORMATION

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

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

**Carcinogenic: Category 3**

**Toxic to Reproduction: Category 2**

**Xn - Harmful**

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

**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 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

**Revision date:**

14-Apr-2015

**Prepared by:**

Product Stewardship Hazard Communication

**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