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

Material Name: Phenytoin Oral Suspension (30 mg/5mL; 37.5 mg/5mL)

Trade Name: Dilantin®; Epanutin®; Epamin®

Chemical Family: Mixture

Intended Use: Pharmaceutical product used for seizures and epilepsy.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>57-41-0</td>
<td>200-328-6</td>
<td>0.6-0.75</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana Flavor</td>
<td>Not Assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Carmoisine red E122</td>
<td>3567-69-9</td>
<td>222-657-4</td>
<td>*</td>
</tr>
<tr>
<td>Citric Acid Monohydrate</td>
<td>5949-29-1</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>2783-94-0</td>
<td>220-491-7</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-8</td>
<td>*</td>
</tr>
<tr>
<td>Orange Oil</td>
<td>Not Assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 40</td>
<td>9005-66-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>*</td>
</tr>
<tr>
<td>Vanillin</td>
<td>121-33-5</td>
<td>204-465-2</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Orange suspension

Signal Word: WARNING

Statement of Hazard: Suspected of causing cancer.

Additional Hazard Information:
Material Name: Phenytoin Oral Suspension (30 mg/5mL; 37.5 mg/5mL)
Revision date: 18-Jan-2007

Short Term: May cause eye irritation (based on components).
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: Not classified


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: Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.

Storage Conditions: Protect from freezing. Protect from light.

Storage Temperature: Store at controlled room temperature 20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ethyl alcohol (ethanol)

OSHA - Final PELS - TWAs:  
= 1000 ppm TWA
= 1900 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

Australia TWA  
= 1000 ppm TWA
= 1880 mg/m³ TWA

Phenytoin

Pfizer OEL TWA-8 Hr:  
0.4 mg/m³

Glycerol

OSHA - Final PELS - TWAs:  
= 15 mg/m³ TWA  total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

Australia TWA  
= 10 mg/m³ TWA

Sucrose

OSHA - Final PELS - TWAs:  
= 15 mg/m³ TWA  total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)

Australia TWA  
= 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Suspension</th>
<th>Color:</th>
<th>Orange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light and freezing.
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.

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

**Sodium benzoate**
- Rat Oral LD50 4,070 mg/kg
- Mouse Oral LD50 1600 mg/kg

**Carboxymethylcellulose sodium**
- Mouse Oral LD50 > 27,000 mg/kg
- Rat Oral LD50 27,000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

**Sucrose**
- Rat Oral LD50 29.7 g/kg

**Ethyl alcohol (ethanol)**
- Mouse Oral LD50 3450 mg/kg
- Rat Oral LD50 7060 mg/kg
- Rat Inhalation LC50 10h 20,000 ppm

**Vanillin**
- Rat Oral LD50 1580 mg/kg

**FD&C Yellow No. 6; (Sunset yellow)**
- Rat Oral LD50 > 10,000 mg/kg
- Mouse Oral LD50 > 6,000 mg/kg

**Glycerol**
- Rat Oral LD50 12600 mg/kg

**Phenytoin**
- Mouse Oral LD50 150 mg/kg
Material Name: Phenytoin Oral Suspension (30 mg/5mL; 37.5 mg/5mL)  
Revision date: 18-Jan-2007  
Page 5 of 9  
Version: 1.4

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.

Irritation / Sensitization: (Study Type, Species, Severity)

- Ethyl alcohol (ethanol)
  - Eye Irritation: Rabbit, Severe

Glycerol

- Skin Irritation: Rabbit, Mild
- Eye Irritation: Rabbit, Mild

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

Sodium benzoate

- 10 Day(s): Rat, Oral, 27370 mg/kg, LOAEL, Liver, Blood
- 10 Day(s): Mouse, Oral, 45 g/kg, LOAEL, Liver, Kidney, Blood, Ureter, Bladder

Carboxymethylcellulose sodium

- 13 Week(s): Rat, Oral, 227 g/kg, LOAEL, Liver, Kidney, Ureter, Bladder

Glycerol

- 28 Day(s): Rat, Oral, 16800 mg/kg, LOAEL, Endocrine system

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

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

Sodium benzoate

- Embryo / Fetal Development: Rat, Oral, 44 g/kg, LOEL, Developmental toxicity

Glycerol

- Reproductive & Fertility-Males: Rat, Oral, 100 mg/kg, LOEL, Fertility

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
MATERIAL SAFETY DATA SHEET

Material Name: Phenytoin Oral Suspension (30 mg/5mL; 37.5 mg/5mL)
Revision date: 18-Jan-2007

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)

Ethyl alcohol (ethanol)
Rainbow Trout LC50/96h 12,900-15,300 mg/L

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 Indication of danger:** Not classified

**OSHA Label:**
WARNING
Suspected of causing cancer.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 2, Subdivision A

Ethyl alcohol (ethanol)
- California Proposition 65
  - Inventory - United States TSCA - Sect. 8(b)
  - Australia (AICS):
  - EU EINECS List
- Developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
- Present
- Present
- 200-578-6

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

Glycerol
- Inventory - United States TSCA - Sect. 8(b)
- Australia (AICS):
- EU EINECS List
- Present
- Present
- 200-289-5

Sucrose
- Inventory - United States TSCA - Sect. 8(b)
- Australia (AICS):
- EU EINECS List
- Present
- Present
- 200-334-9

Carboxymethylcellulose sodium
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