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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Phenytoin Oral Suspension (100mg/5ml; 125mg/5ml)

Trade Name: Dilantin®; Dilantin-125®; Epanutin®; Epamin®; Epelin®

Chemical Family: Mixture

Intended Use: Pharmaceutical product used for seizures and epilepsy.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>*</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>57-41-0</td>
<td>200-328-6</td>
<td>2.25</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>&lt; 1</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>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>Concentrated orange oil</td>
<td>8008-57-9</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Imitation banana oil</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>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>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
Material Name: Phenytoin Oral Suspension (100mg/5ml; 125mg/5ml)
Revision date: 18-Jan-2007

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:
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:
Carcinogenic: Category 3

EU Hazard Symbols:

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect

Australian Hazard Classification (NOHSC):

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 turnout 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

Glycerin, USP
- OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
- ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
- Australia TWA = 10 mg/m³ TWA

Phenytoin
- Pfizer OEL TWA-8 Hr: 0.4 mg/m³

Ethyl alcohol (ethanol)
- OSHA - Final PELS - TWAs: = 1000 ppm TWA
- ACGIH Threshold Limit Value (TWA) = 1900 mg/m³ TWA
- Australia TWA = 1000 ppm TWA
- = 1880 mg/m³ TWA

Sucrose
- OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
- ACGIH Threshold Limit Value (TWA) = 5 mg/m³ 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>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Orange</td>
</tr>
<tr>
<td>Physical State:</td>
<td>Suspension</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Orange</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
Material Name: Phenytoin Oral Suspension (100mg/5ml; 125mg/5ml)
Revision date: 18-Jan-2007

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

Citric acid, anhydrous
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Mild

Glycerin, USP
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

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

Phenytoin
Embryo / Fetal Development  Mouse  Oral  75 mg/kg/day  NOEL  Maternal toxicity, Fetotoxicity, Teratogenic
Material Name: Phenytoin Oral Suspension (100mg/5ml; 125mg/5ml)
Revision date: 18-Jan-2007

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

FD&C Yellow No. 6; (Sunset yellow)
IARC:  Group 3

Phenytoin
IARC:  Group 2B
NTP:  Reasonably Anticipated To Be A Carcinogen
OSHA:  Present

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

Glycerin, USP
Oncorhynchus mykiss (Rainbow Trout)  LD50  96 Hours  50 mg/L
Daphnia Magna (Water Flea)  EC50  24 Hours  >500 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 Symbol: Xn
EU Indication of danger: Carcinogenic: Category 3
EU Risk Phrases: R40 - Limited evidence of a carcinogenic effect
EU Safety Phrases: 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:
Class D, Division 2, Subdivision A

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

Citric acid, anhydrous
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 201-069-1

Concentrated orange oil
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5

Phenytoin
CERCLA/SARA 313 Emission reporting = 0.1 % de minimis concentration
California Proposition 65 carcinogen, initial date 1/1/88
devvelopmental 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

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

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

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

FD&C Yellow No. 6; (Sunset yellow)
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 220-491-7

Magnesium aluminum silicate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 215-478-8

Polysorbate 40
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

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

Sodium benzoate
Inventory - United States TSCA - Sect. 8(b) Present
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