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

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. HAZARDS IDENTIFICATION

Appearance: Orange suspension
Signal Word: DANGER

Statement of Hazard: Suspected of causing cancer.
May damage the unborn child.

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 Classification
EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction: Category 2

EU Hazard Symbols: T

EU Risk Phrases:
2. HAZARDS IDENTIFICATION

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

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.

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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>57-41-0</td>
<td>200-328-6</td>
<td>Carc.Cat.3;R40 Repr.Cat.2;R61 Xn;R22</td>
<td>2-2.5</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F;R11</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentrated orange oil</td>
<td>8008-57-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Imitation banana oil</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 40</td>
<td>9005-66-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Vanillin</td>
<td>121-33-5</td>
<td>204-465-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-8</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

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

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

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. 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: Protect from freezing. Protect from light. Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Glycerin, USP

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Finland OEL - TWA Listed
France OEL - TWA Listed

SUSPENSION
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Euro-specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenytoin</td>
<td>Listed</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>Listed</td>
</tr>
<tr>
<td>Sucrose</td>
<td>Listed</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>Listed</td>
</tr>
</tbody>
</table>

#### Phenytoin

- **Pfizer OEL TWA-8 Hr:** 400 µg/m³

#### Magnesium aluminum silicate

- Bulgaria OEL - TWA
- Czech Republic OEL - TWA

#### Sucrose

- **ACGIH Threshold Limit Value (TWA):** 10 mg/m³ TWA
- **Australia TWA:** 10 mg/m³
- **Belgium OEL - TWA:** Listed
- **Bulgaria OEL - TWA:** Listed
- **Estonia OEL - TWA:** Listed
- **France OEL - TWA:** Listed
- **Ireland OEL - TWAs:** Listed 15 mg/m³ total 5 mg/m³
- **Latvia OEL - TWA:** Listed
- **Lithuania OEL - TWA:** Listed
- **OSHA - Final PELS - TWAs:** 15 mg/m³ total 5 mg/m³
- **Portugal OEL - TWA:** Listed
- **Spain OEL - TWA:** Listed

#### Ethyl alcohol (ethanol)

- **ACGIH Threshold Limit Value (TWA):** 1000 ppm TWA
- **ACGIH OELs - Notice of Intended Changes:** Listed
- **Australia TWA:** 1000 ppm 1880 mg/m³
- **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
- **France OEL - TWA:** Listed
- **Germany - TRGS 900 - TWAs:** 500 ppm 960 mg/m³
- **Germany (DFG) - MAK:** 500 ppm MAK 960 mg/m³ MAK
- **Greece OEL - TWA:** Listed
- **Hungary OEL - TWA:** Listed
- **Ireland OEL - TWAs:** Listed
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**The exposure limit(s) listed for solid components are only relevant if dust or mist 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:** Suspension
- **Molecular Formula:** Mixture
- **Color:** Orange
- **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.

**Acute Toxicity:** (Species, Route, End Point, Dose)
11. TOXICOLOGICAL INFORMATION

**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  LD 50  1580 mg/kg

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

**Citric acid, anhydrous**
Rat  Oral  LD50  3000 mg/kg

**Glycerin, USP**
Mouse  Oral  LD50  4090 mg/kg
Rat  Oral  LD50  12.6 g/kg
Rabbit  Dermal  LD50  > 10 g/kg
Rat  Inhalation  LC50 1hr  > 570 mg/m³
Rat  Dermal  LD 50  >21.9 g/kg

**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

**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
Skin Irritation  Rabbit  Mild

**Citric acid, anhydrous**
Eye Irritation  Rabbit  Severe
11. TOXICOLOGICAL INFORMATION

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
- 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)

**Sucrose**
- Bacterial Mutagenicity (Ames)  *Salmonella*  Negative

**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
11. TOXICOLOGICAL INFORMATION

Carcinogen Status: See below

Ethyl alcohol (ethanol)
IARC: Group 1
NTP: Listed
OSHA: Present

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

Phenytoin
IARC: Group 2B
NTP: Listed
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)
*Oncorhynchus mykiss* (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

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: 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.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Suspected of causing cancer.
May damage the unborn child.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

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

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

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

Polysorbate 40
- Inventory - United States TSCA - Sect. 8(b): Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanillin</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>204-465-2</td>
</tr>
<tr>
<td>Phenytoin</td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>0.1% de minimis concentration</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>carcinogen, initial date 1/1/88</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>for Drugs and Poisons:</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-328-6</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>201-069-1</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>208-534-8</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-478-8</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>220-491-7</td>
</tr>
<tr>
<td>Purified water</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Sucrose</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-334-9</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td></td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

California Proposition 65
- Carcinogen, initial date 7/1/88 (when associated with alcohol abuse)
- Developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)

Inventory - United States TSCA - Sect. 8(b)
- Listed

Australia (AICS):
- Listed

EU EINECS/ELINCS List
- 200-578-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
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. Publicly available toxicity information.

Reasons for Revision:
- Updated Section 2 - Hazard Identification.
- Updated Section 3 - Composition / Information on Ingredients.
- Updated Section 8 - Exposure Controls / Personal Protection.
- Updated Section 10 - Stability and Reactivity.
- Updated Section 15 - Regulatory Information.
- Updated Section 4 - First Aid Measures.
- Updated Section 7 - Handling and Storage.

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