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

Product Identifier

Material Name: Phenytoin Oral Suspension

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

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>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F; R11</td>
<td>Flam. Liq. 2 (H225)</td>
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<td>Phenytoin</td>
<td>57-41-0</td>
<td>200-328-6</td>
<td>Carc.Cat.3;R40</td>
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<td>Repr.Cat.2;R61</td>
<td>Carc. 2 (H351)</td>
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<td>Xn;R22</td>
<td>Repr 1B (H360D)</td>
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<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
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<td>*</td>
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</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**

SUSPENSION
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.

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: Formation of toxic gases is possible during heating or fire.
Products:
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
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.
Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Protect from freezing. Protect from light. 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.

Glycerin, USP
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Czech Republic OEL - TWA: 10 mg/m³
- Estonia OEL - TWA: 10 mg/m³
- Finland OEL - TWA: 20 mg/m³
- France OEL - TWA: 10 mg/m³
- Germany (DFG) - MAK: 50 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Poland OEL - TWA: 10 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL - TWAs: 50 mg/m³

Ethyl alcohol (ethanol)
- ACGIH Threshold Limit Value (STEL): 1000 ppm
- Australia TWA: 1000 ppm
- Austria OEL - MAKs: 1000 ppm
- Belgium OEL - TWA: 1000 ppm
- Bulgaria OEL - TWA: 1000.0 mg/m³
- Czech Republic OEL - TWA: 1000 mg/m³
- Denmark OEL - TWA: 1000 ppm
- Estonia OEL - TWA: 500 ppm
- Finland OEL - TWA: 1000 ppm
- France OEL - TWA: 1000 ppm
- Germany - TRGS 900 - TWAs: 500 ppm
- Germany (DFG) - MAK: 500 ppm
- Greece OEL - TWA: 1000 ppm
- Hungary OEL - TWA: 1900 mg/m³
- Latvia OEL - TWA: 1000 mg/m³
- Lithuania OEL - TWA: 500 ppm
- Netherlands OEL - TWA: 260 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| Engineering Controls: | OSHA - Final PELS - TWAs: | 1000 ppm |
| | | 1900 mg/m³ |
| | Poland OEL - TWA | 1900 mg/m³ |
| | Portugal OEL - TWA | 1000 ppm |
| | Romania OEL - TWA | 1000 ppm |
| | Russia OEL - TWA | 1000 mg/m³ |
| | Slovakia OEL - TWA | 500 ppm |
| | Slovenia OEL - TWA | 1000 ppm |
| | Spain OEL - TWA | 1000 ppm |
| | Sweden OEL - TWAs | 500 ppm |
| | Switzerland OEL - TWAs | 500 ppm |
| | Vietnam OEL - TWAs | 1000 mg/m³ |

Phenytoin

| Pfizer OEL TWA-8 Hr: | 400 µg/m³ |

Sucrose

| ACGIH Threshold Limit Value (TWA) | 10 mg/m³ |
| Australia TWA | 10 mg/m³ |
| Belgium OEL - TWA | 10 mg/m³ |
| Bulgaria OEL - TWA | 10.0 mg/m³ |
| Estonia OEL - TWA | 10 mg/m³ |
| France OEL - TWA | 10 mg/m³ |
| Ireland OEL - TWAs | 10 mg/m³ |
| Latvia OEL - TWA | 5 mg/m³ |
| Lithuania OEL - TWA | 10 mg/m³ |
| OSHA - Final PELS - TWAs: | 15 mg/m³ |
| Portugal OEL - TWA | 10 mg/m³ |
| Slovakia OEL - TWA | 6 mg/m³ |
| Spain OEL - TWA | 10 mg/m³ |

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


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

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<thead>
<tr>
<th>Physical State:</th>
<th>Suspension</th>
<th>Color:</th>
<th>Orange</th>
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<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</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)

Polymerization: Will not occur

**SUSPENSION**

Material Name: Phenytoin Oral Suspension

Physical State: Suspension
Color: Orange
Odor: No data available
Odor Threshold: No data available
Molecular Formula: Mixture
Molecular Weight: Mixture

**Suspending Agents**
- Citric acid, anhydrous
- Polysorbate 40
- Glycerin, USP
- Magnesium aluminum silicate
- Sodium benzoate
- Carboxymethylcellulose sodium
- FD&C Yellow No. 6; (Sunset yellow)
- Ethyl alcohol (ethanol)
- Sucrose
- Vanillin
- Purified water
- Imitation banana oil
- Concentrated orange oil
- Citric acid, anhydrous
- Glycerin, USP
- Magnesium aluminum silicate
- Phenytoin

**Phenyltoin**
Predicted log D 7.4 2.47
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: 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.
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.

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

Sodium benzoate
  Rat Oral LD50 4,070 mg/kg
  Mouse Oral LD50 1600mg/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 7060mg/kg
  Rat Inhalation LC50 10h 20,000ppm

Vanillin
**11. TOXICOLOGICAL INFORMATION**

**Ethyl alcohol (ethanol)**
- 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

**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 1635mg/kg
- Rat Intravenous LD 50 96mg/kg
- Rat IM LD 50 >337mg/kg
- Rabbit Oral LD 50 >3000mg/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
- 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
11. TOXICOLOGICAL INFORMATION

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

Carcinogen Status:
See below

Ethyl alcohol (ethanol)
IARC:  Group 1 (Carcinogenic to Humans)

FD&C Yellow No. 6; (Sunset yellow)
IARC:  Group 3 (Not Classifiable)

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

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)

**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**
*Hyalela 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:
Class D, Division 2, Subdivision A

Glycerin, USP
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 V - Exemptions from the obligations of Register:
Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern

EU EINECS/ELINCS List
200-289-5

Concentrated orange oil
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
EU EINECS/ELINCS List Not Listed

Imitation banana oil
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List Not Listed

Citric acid, anhydrous
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 201-069-1

Carboxymethylcellulose sodium
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance Description</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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<td>231-791-2</td>
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</table>
15. REGULATORY INFORMATION

Sodium benzoate

| 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               | 208-534-8  |

Sucrose

| 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               | 200-334-9  |

Vanillin

| 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               | 204-465-2  |

16. OTHER INFORMATION

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

- Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
- 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

F - Highly flammable
Carcinogenic: Category 3
Toxic to Reproduction: Category 2
Xn - Harmful

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

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