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

Product Identifier

Material Name: Tafamidis Capsules
Trade Name: VYNAQEL
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Global Manufacturing
38-42 Wharf Road
West Ryde, New South Wales 2114
Australia
(02) 9850 3333
Ask for Environmental Health & Safety Manager

Emergency telephone number (North America):
Chemtrec (24 hours): 1-800-424-9300

Emergency telephone number (Australia):
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

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
Precautionary Statements: P201 - Obtain special instructions before use
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

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

#### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium hydroxide</td>
<td>1336-21-6</td>
<td>215-647-6</td>
<td>Skin Corr. 1B (H314) Aquatic Acute 1 (H400)</td>
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<td>ETHYL ALCOHOL</td>
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<td>200-578-6</td>
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<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
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<td>Glycerin, USP</td>
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<td>200-289-5</td>
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<tr>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)</td>
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<td>Polyethylene glycol 400</td>
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<tr>
<td>Tafamidis Meglumine</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
</tr>
</thead>
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<td>215-527-3</td>
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<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>Not Listed</td>
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<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
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<td>Polysorbate 80</td>
<td>9005-65-6</td>
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<tr>
<td>Polyvinyl Acetate Phthalate</td>
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<td>Sorbitan monooleate</td>
<td>1338-43-8</td>
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<td>Sorbitol</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 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 firefighting 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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup 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 thoroughly after handling. 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**ETHYL ALCOHOL**

<table>
<thead>
<tr>
<th>Country</th>
<th>Measure</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1880 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
<td></td>
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<tr>
<td>Belgium OEL - TWA</td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
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</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
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<td></td>
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<tr>
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<tr>
<td></td>
<td>960 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>960 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>1000 ppm</td>
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<td></td>
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<td>Hungary OEL - TWA</td>
<td>1900 mg/m³</td>
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</tr>
<tr>
<td>Latvia OEL - TWA</td>
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<tr>
<td>Lithuania OEL - TWA</td>
<td>500 ppm</td>
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<tr>
<td></td>
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<td></td>
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<tr>
<td>Netherlands OEL - TWA</td>
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<td>OSHA - Final PELs - TWAs</td>
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<tr>
<td></td>
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</tr>
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</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
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<tr>
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**Glycerin, USP**

<table>
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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
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<tr>
<th>Country</th>
<th>Unit</th>
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</tr>
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<td>Germany (DFG) - MAK</td>
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<tr>
<td>Greece OEL - TWA</td>
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<td>10</td>
</tr>
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<td>Ireland OEL - TWAs</td>
<td>mg/m³</td>
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<tr>
<td>OSHA - Final PELS - TWAs:</td>
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<td>15</td>
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<td>Portugal OEL - TWA</td>
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Isopropyl alcohol

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<tr>
<td></td>
<td>mg/m³</td>
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<tr>
<td></td>
<td>mg/m³</td>
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</tr>
<tr>
<td>Germany - Biological Exposure Limit:</td>
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<td>Hungary OEL - TWA</td>
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<td>Ireland OEL - TWAs</td>
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<td>Japan - OELs - Ceilings</td>
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<td>ppm</td>
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<td></td>
<td>mg/m³</td>
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<tr>
<td>OSHA - Final PELS - TWAs:</td>
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<td>mg/m³</td>
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<td>ppm</td>
<td>200</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>ppm</td>
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<tr>
<td></td>
<td>mg/m³</td>
<td>200</td>
</tr>
<tr>
<td>Romania - Biological Exposure Limit:</td>
<td>mg/L</td>
<td>50</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:
Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
<th>Color:</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<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>
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</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) |
Tafamidis Meglumine
No data available
Polysorbate 80
No data available
Gelatin
No data available
Glycerin, USP
No data available
Polyethylene glycol 400
No data available
Ammonium hydroxide
No data available
FD & C Blue No. 1
No data available
Carmine lake
No data available
ETHYL ALCOHOL
No data available
Ferric oxide yellow
No data available
Isopropyl alcohol

PZ01480
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Sorbitan monooleate
No data available

Sorbitol
No data available

Titanium dioxide
No data available

Polyvinyl Acetate Phthalate
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:
  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 following information is available for the individual ingredients.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include headache, sleepiness (somnolence), infection, gastrointestinal disturbances, insomnia, muscle pain

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

Polysorbate 80
  Rat  Intravenous  LD 50  1790 mg/kg
  Mouse  Oral  LD 50  25 g/kg

Glycerin, USP
  Mouse  Oral  LD50  4090 mg/kg
  Rat  Oral  LD50  12.6 g/kg
11. TOXICOLOGICAL INFORMATION

Rat  Dermal  LD50  >  10 g/kg
Rat  Inhalation  LC50 1hr  >  570 mg/m³
Rat  Dermal  LD50  >  21.9 g/kg

Ammonium hydroxide
Rat  Oral  LD50  350 mg/kg

ETHYL ALCOHOL
Rat  Oral  LD50  7060 mg/kg
Rat  IV  LD50  1440mg/kg
Rat  Inhalation  LC 50  124700mg/m³

Isopropyl alcohol
Rat  Oral  LD50  >  2000 mg/kg
Mouse  Oral  LD50  3600 mg/kg
Rat  Inhalation  LC50-8h  16,000 ppm
Rabbit  Dermal  LD50  12800 mg/kg
Rat  Inhalation  LC50  30mg/L

Titanium dioxide
Rat  Oral  LD50  >  7500 mg/kg
Rat  Subcutaneous  LD50  50 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)

Tafamidis Meglumine
Eye Irritation  (In vitro, BCOP)  Not applicable  Mild
Skin Corrosivity  (In vitro, RHE)  Not applicable  Negative
Eye Irritation  Rabbit  Minimal
Skin Irritation  Rabbit  Negative
Skin Sensitization - LLNA  Mouse  Negative

Glycerin, USP
Eye Irritation  Rabbit  Mild

Polyethylene glycol 400
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Ammonium hydroxide
Eye Irritation  Rabbit  Severe

Isopropyl alcohol
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

### Tafamidis Meglumine

**28 Day(s)**
- **Species:** Mouse
- **Route:** Oral
- **Dose:** 10 mg/kg/day
- **Effect:** NOAEL Liver

**28 Day(s)**
- **Species:** Rat
- **Route:** Oral
- **Dose:** 30 mg/kg/day
- **Effect:** NOAEL Thymus, Gastrointestinal system

**13 Week(s)**
- **Species:** Rat
- **Route:** Oral
- **Dose:** 30 mg/kg/day
- **Effect:** NOAEL None identified

**28 Day(s)**
- **Species:** Dog
- **Route:** Oral
- **Dose:** 10 mg/kg/day
- **Effect:** NOAEL Gastrointestinal system, Liver

**39 Week(s)**
- **Species:** Dog
- **Route:** Oral
- **Dose:** 45 mg/kg/day
- **Effect:** NOAEL None identified

**26 Week(s)**
- **Species:** Rat
- **Route:** Oral
- **Dose:** 30 mg/kg/day
- **Effect:** NOAEL No effects at maximum dose

**28 Day(s)**
- **Species:** Mouse
- **Route:** Oral
- **Dose:** 120 mg/kg/day
- **Effect:** LOAEL Liver Lymphoid tissue

**20 Week(s)**
- **Species:** Rat
- **Route:** Inhalation
- **Dose:** 4000 ppm
- **Effect:** NOAEL Liver, Central nervous system

**104 Week(s)**
- **Species:** Rat
- **Route:** Inhalation
- **Dose:** 5000 ppm
- **Effect:** Kidney

**26 Week(s)**
- **Species:** Mouse
- **Route:** Oral
- **Dose:** 30 mg/kg/day
- **Effect:** NOAEL None identified

**39 Week(s)**
- **Species:** Dog
- **Route:** Oral
- **Dose:** 45 mg/kg/day
- **Effect:** NOAEL None identified

**28 Day(s)**
- **Species:** Mouse
- **Route:** Oral
- **Dose:** 10 mg/kg/day
- **Effect:** NOAEL Gastrointestinal system

### Isopropyl alcohol

**28 Day(s)**
- **Species:** Dog
- **Route:** Oral
- **Dose:** 10 mg/kg/day
- **Effect:** NOAEL Gastrointestinal system, Liver

**Bacterial Mutagenicity (Ames)**
- **Organism:** Salmonella, E. coli
- **Result:** Negative

**Chromosome Aberration**
- **Organism:** Human Lymphocytes
- **Result:** Negative

**In Vivo Micronucleus**
- **Organism:** Rat Bone Marrow
- **Result:** Negative

**Isopropyl alcohol**

**Prenatal & Postnatal Development**
- **Species:** Rat
- **Route:** Inhalation
- **Dose:** 7,000 ppm
- **Effect:** LOAEL Maternal toxicity, Fetotoxicity, Embryotoxicity

**2 Generation Reproductive Toxicity**
- **Species:** Rat
- **Route:** Oral
- **Dose:** 1000 mg/kg/day
- **Effect:** LOAEL Maternal Toxicity, Fetal mortality

**Prenatal & Postnatal Development**
- **Species:** Rat
- **Route:** Oral
- **Dose:** 1200 mg/kg/day
- **Effect:** NOAEL No effects at maximum dose

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

**Tafamidis Meglumine**

**Bacterial Mutagenicity (Ames)**
- **Organisms:** Salmonella
- **Result:** Negative

**Chromosome Aberration**
- **Organism:** Human lymphocytes
- **Result:** Negative

**In Vivo Micronucleus**
- **Organism:** Rat bone marrow
- **Result:** Negative

**Isopropyl alcohol**

**Bacterial Mutagenicity (Ames)**
- **Organism:** Salmonella
- **Result:** Negative

**Mammalian Cell Mutagenicity**
- **Organism:** HGPRT Chinese hamster ovary (CHO) cells
- **Result:** Negative

**In Vitro Sister Chromatid Exchange**
- **Result:** Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Tafamidis Meglumine**

**26 Week(s)**
- **Species:** Mouse
- **Route:** Oral
- **Dose:** 90 mg/kg/week
- **Effect:** NOAEL None identified

**Carcinogen Status:** See below

**FD & C Blue No. 1**
**11. TOXICOLOGICAL INFORMATION**

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYL ALCOHOL</td>
<td>Group 1 (Carcinogenic to Humans)</td>
</tr>
<tr>
<td>Pimephales promelas</td>
<td>LC50 96 Hours 8.2 mg/L</td>
</tr>
<tr>
<td><strong>Isopropyl alcohol</strong></td>
<td>Group 3 (Not Classifiable)</td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong></td>
<td>Group 2B (Possibly Carcinogenic to Humans)</td>
</tr>
</tbody>
</table>

**12. ECOLOGICAL INFORMATION**

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been investigated.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

- **Glycerin, USP**
  - *Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 50 mg/L
  - *Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

- **Ammonium hydroxide**
  - *Daphnia magna* (Water Flea) LC50 48 Hours 0.66 mg/L
  - *Lepomis macrochirus* (Bluegill Sunfish) LC50 48 Hours 0.024 mg/L
  - *Pimephales promelas* (Fathead Minnow) LC50 96 Hours 8.2 mg/L

- **ETHYL ALCOHOL**
  - *Brachydanio rerio* (Zebra fish) OECD NOEC 42 Hours 500 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**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, ADG or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

### Ammonium hydroxide
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 1000 lb, 454 kg
- **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**: 215-647-6

### Carmine lake
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **EU EINECS/ELINCS List**: 215-527-3

### ETHYL ALCOHOL
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**:
  - CEC: carcinogen 4/29/2011 in alcoholic beverages
  - Developmental toxicity: 10/1/1987 in alcoholic beverages
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 200-578-6

### FD & C Blue No. 1
- **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**: 223-339-8

### Ferric oxide yellow
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
15. REGULATORY INFORMATION

Isopropyl alcohol
- 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: 200-661-7

Polyethylene glycol 400
- 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 2
- EU EINECS/ELINCS List: Not Listed

Polysorbate 80
- 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: 500-019-9

Polyvinyl Acetate Phthalate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>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>
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<td>Not Listed</td>
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<td>Present</td>
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<tr>
<td>Tafamidis Meglumine</td>
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<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
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<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
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<td></td>
<td>carcinogen 9/2/2011 airborne, unbound particles of respirable size</td>
<td>Present</td>
<td>236-675-5</td>
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<tr>
<td>California Proposition 65</td>
<td></td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
<td>Australia (AICS):</td>
<td>Present</td>
<td>EU EINECS/ELINCS List</td>
<td>236-675-5</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
- Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
- Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
- Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
- Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness
- Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 11 - Toxicology Information. Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

Revision date: 06-May-2019

Prepared by: Product Stewardship Hazard Communications

Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet