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

Product Identifier

Material Name: Disopyramide Phosphate Capsules
Trade Name: Norpace
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as anti-arrhythmic

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Reproductive Toxicity: Category 1B

Label Elements

Signal Word: Danger
Hazard Statements:
H302 - Harmful if swallowed
H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P308+P313 - IF exposed or concerned: Get medical attention/advice
P330 - Rinse mouth
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

<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>Disopyramide Phosphate</td>
<td>22059-60-5</td>
<td>244-756-1</td>
<td>Acute Tox.4 (H302) Repr.1B (H360Fd)</td>
<td>100 / 150 mg ***</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Red No. 3 (E 127)</td>
<td>16423-68-0</td>
<td>240-474-8</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>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

*** per tablet/capsule/lozenge/suppository
* 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:** Not applicable

**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 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:** 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.

**Disopyramide Phosphate**

**Pfizer OEL TWA-8 Hr:** 250µg/m³

**Talc (non-asbestiform)**

<table>
<thead>
<tr>
<th>Material</th>
<th>OEL/TWA/PEL</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACGIH Threshold Limit Value (TWA)</strong></td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Australia TWA</strong></td>
<td></td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td><strong>Austria OEL - MAKs</strong></td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Belgium OEL - TWA</strong></td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Bulgaria OEL - TWA</strong></td>
<td></td>
<td>1.0 fiber/cm³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td><strong>Czech Republic OEL - TWA</strong></td>
<td></td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td><strong>Denmark OEL - TWA</strong></td>
<td></td>
<td>0.3 fiber/cm³</td>
</tr>
<tr>
<td><strong>Finland OEL - TWA</strong></td>
<td></td>
<td>0.5 fiber/cm³</td>
</tr>
<tr>
<td><strong>Greece OEL - TWA</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Hungary OEL - TWA</strong></td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Ireland OEL - TWAs</strong></td>
<td></td>
<td>10 mg/m³</td>
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<tr>
<td></td>
<td></td>
<td>0.8 mg/m³</td>
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<tr>
<td><strong>Lithuania OEL - TWA</strong></td>
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<tr>
<td></td>
<td></td>
<td>1 mg/m³</td>
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<tr>
<td><strong>Netherlands OEL - TWA</strong></td>
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<tr>
<td><strong>OSHA - Final PELs - Table Z-3 Mineral D:</strong></td>
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<tr>
<td><strong>Poland OEL - TWA</strong></td>
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<td>4.0 mg/m³</td>
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<tr>
<td></td>
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<td>1.0 mg/m³</td>
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<tr>
<td><strong>Portugal OEL - TWA</strong></td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Romania OEL - TWA</strong></td>
<td></td>
<td>2 mg/m³</td>
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<tr>
<td><strong>Slovakia OEL - TWA</strong></td>
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<tr>
<td><strong>Slovenia OEL - TWA</strong></td>
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<tr>
<td><strong>Spain OEL - TWA</strong></td>
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<tr>
<td><strong>Sweden OEL - TWAs</strong></td>
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<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td><strong>Switzerland OEL - TWAs</strong></td>
<td></td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

**Titanium dioxide**

<table>
<thead>
<tr>
<th>Material</th>
<th>OEL/TWA/PEL</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACGIH Threshold Limit Value (TWA)</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Australia TWA</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Austria OEL - MAKs</strong></td>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Belgium OEL - TWA</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Bulgaria OEL - TWA</strong></td>
<td></td>
<td>10.0 mg/m³</td>
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<tr>
<td><strong>Denmark OEL - TWA</strong></td>
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<td>6 mg/m³</td>
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<td><strong>Estonia OEL - TWA</strong></td>
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<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>France OEL - TWA</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td><strong>Greece OEL - TWA</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Ireland OEL - TWAs</strong></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td><strong>Latvia OEL - TWA</strong></td>
<td></td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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). 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.

Analytical Method:

Analytical method available for Disopyramide Phosphate. Contact Pfizer Inc for further information.

Exposure Controls

- 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.)
- 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.)
- 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.)

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.)

### Analytical Method

Analytical method available for Disopyramide Phosphate. Contact Pfizer Inc for further information.

### 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). 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>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
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</tr>
<tr>
<td>Water Solubility:</td>
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<tr>
<td>pH:</td>
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<tr>
<td>Melting/Freezing Point (°C):</td>
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<tr>
<td>Boiling Point (°C):</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>FD &amp; C Red No. 3 (E 127)</td>
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<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>No data available</td>
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<tr>
<td>Gelatin</td>
<td>No data available</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>No data available</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>No data available</td>
</tr>
<tr>
<td>Disopyramide Phosphate</td>
<td>No data available</td>
</tr>
<tr>
<td>Lactose</td>
<td>No data available</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>No data available</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
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</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
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<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
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<td>Vapor Pressure (kPa):</td>
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<tr>
<td>Vapor Density (g/ml):</td>
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</tr>
<tr>
<td>Relative Density:</td>
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<td>Viscosity:</td>
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<td>Flammability:</td>
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<tr>
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<td>Flash Point (Liquid) (°C):</td>
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</tr>
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<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

| Reactivity: | No data available |
| Chemical Stability: | Stable under normal conditions of use |
| Possibility of Hazardous Reactions | No data available |
| 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 |
10. STABILITY AND REACTIVITY

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.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Clinical use of this drug has caused dry mouth, blurred vision, difficulty with urination, lack of urination, constipation, increased heart rate (tachycardia), irregular heartbeat (cardiac arrhythmia), decrease in blood pressure (hypotension). Can produce impotence and other sexual disturbances in men.

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

FD & C Red No. 3 (E 127)
- Rat Oral LD50 1840 mg/kg
- Mouse Oral LD50 1264 mg/kg

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

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

Disopyramide Phosphate
- Rat Oral LD50 333-580 (F) mg/kg
- Rat Oral LD50 333-888 (M) mg/kg

Talc (non-asbestiform)
- Rat Oral LD50 > 1600 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.

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

Disopyramide Phosphate
- 4 Week(s) Rat Oral 300 mg/kg/day LOAEL Central nervous system
- 5 Week(s) Dog Intravenous 315 mg/kg/day LOAEL Central Nervous System
- 40 Week(s) Rat 400 mg/kg/day NOAEL None identified
- 1 Year(s) Dog 100 mg/kg/day NOAEL None identified
- 78 Week(s) Rat 400 mg/kg/day NOAEL None identified

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

Disopyramide Phosphate
- Reproductive & Fertility Rat 250 mg/kg/day NOAEL No effects at maximum dose
- Embryo / Fetal Development Rat 250 mg/kg/day LOAEL Maternal Toxicity, Embryotoxicity, Fetotoxicity
- Embryo / Fetal Development Rabbit 60 mg/kg/day LOAEL Fetotoxicity

PZ00363


11. TOXICOLOGICAL INFORMATION

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

Disopyramide Phosphate
Bacterial Mutagenicity (Ames)  
Salmonella  Negative

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

Disopyramide Phosphate
Not specified  Rat  No route specified  400  NOEL  Not carcinogenic

Carcinogen Status:  See below

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

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)

FD & C Blue No. 1
IARC:  Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:  No data available

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, or IMDG regulations.

15. REGULATORY INFORMATION

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

Disopyramide Phosphate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 244-756-1

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

FD & C Red No. 3 (E 127)
- 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: 240-474-8

FD&C Yellow No. 6; (Sunset yellow)
- 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: 220-491-7

Gelatin
- 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: 232-554-6
15. REGULATORY INFORMATION

Lactose
- 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:
  - EU EINECS/ELINCS List: 200-559-2

Talc (non-asbestiform)
- 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: 238-877-9

Titanium dioxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: carcinogen 9/2/2011 airborne, unbound particles of respirable size
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

Corn Starch
- 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:
  - EU EINECS/ELINCS List: 232-679-6

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 22-Oct-2018
Prepared by: Product Stewardship Hazard Communication
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End of Safety Data Sheet