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

Material Name: Disopyramide Phosphate Capsules

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Norpace</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Pharmaceutical product used as anti-arrhythmic</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Capsules

Signal Word: DANGER

Statement of Hazard:
- Harmful if swallowed.
- May damage fertility.
- Suspected of damaging the unborn child.

Additional Hazard Information:

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.

EU Indication of danger:
- Harmful

EU Hazard Symbols:

EU Risk Phrases:
- R22 - Harmful if swallowed.
- R60 - May impair fertility.
- R63 - Possible risk of harm to the unborn child.
2. HAZARDS IDENTIFICATION

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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Disopyramide Phosphate</td>
<td>22059-60-5</td>
<td>244-756-1</td>
<td>Xn; R22</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat. 2; R60</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat. 3; R63</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 / 150 mg ***</td>
<td></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>
</tbody>
</table>

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

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 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.

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: 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Corn Starch

- 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
- Czech Republic OEL - TWA: 4.0 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 5 mg/m³
- OSHA - Final PELS - TWAs: 4 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Slovakia OEL - TWA: 4 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Disopyramide Phosphate**

- **Pfizer OEL TWA-8 Hr:** 250µg/m³

**Talc (non-asbestiform)**

<table>
<thead>
<tr>
<th>Country</th>
<th>Standard</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 fiber/cm³</td>
<td>6.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>2.0 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.3 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
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</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>0.8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
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<tr>
<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
<td>1.0 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
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<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
<td>10 mg/m³</td>
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<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
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<td>Spain OEL - TWA</td>
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</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³</td>
<td>1 mg/m³</td>
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**Titanium dioxide**

<table>
<thead>
<tr>
<th>Country</th>
<th>Standard</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>OSHA - Final PELs - TWAs:</td>
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</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
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</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
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<tbody>
<tr>
<td>Portugal</td>
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</tr>
<tr>
<td>Romania</td>
<td>OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sweden</td>
<td>OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>


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:** Capsule
- **Color:** White / Orange or Brown / orange
- **Molecular Formula:** Mixture
- **Molecular Weight:** Mixture

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)**

**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
## 11. TOXICOLOGICAL INFORMATION

**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

### 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:** None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

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

**Titanium dioxide**
- IARC: Group 2B (Possibly Carcinogenic to Humans)
- OSHA: Listed
11. TOXICOLOGICAL INFORMATION

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.

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: Harmful
Toxic to Reproduction: Category 2
Toxic to Reproduction: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R60 - May impair fertility.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S53 - Avoid exposure - obtain special instructions before use.
15. REGULATORY INFORMATION

OSHA Label:
DANGER
Harmful if swallowed.
May damage fertility.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision B
Class D, Division 2, Subdivision A

Corn Starch
California Proposition 65
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

Disopyramide Phosphate
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 244-756-1

FD & C Blue No. 1
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)
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)
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 220-491-7

Gelatin
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
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<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>Titanium dioxide</td>
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<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>236-675-5</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R60 - May impair fertility.
R63 - Possible risk of harm to 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 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information.

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