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-arrhythmically

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

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

EU Classification:
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.

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
Australian Hazard Classification (NOHSC):

No data available

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>EU Classification</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>Xn;R22 Repr.Cat.2;R60 Repr.Cat.3;R63</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>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>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>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
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<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>Not Listed</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>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>Not Listed</td>
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</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</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>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
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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 R phrases and 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 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 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. Clean up 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)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm³
                        6.0 mg/m³
                        3.0 mg/m³
Czech Republic OEL - TWA 2.0 mg/m³
Denmark OEL - TWA 0.3 fiber/cm³
Finland OEL - TWA 0.5 fiber/cm³
Greece OEL - TWA 10 mg/m³
                        2 mg/m³
Hungary OEL - TWA 2 mg/m³
Ireland OEL - TWAs 10 mg/m³
                        0.8 mg/m³
Lithuania OEL - TWA 2 mg/m³
                        1 mg/m³
Netherlands OEL - TWA 0.25 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Poland OEL - TWA 4.0 mg/m³
                        1.0 mg/m³
Portugal OEL - TWA 2 mg/m³
Romania OEL - TWA 2 mg/m³
Slovakia OEL - TWA 2 mg/m³
                        10 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Titanium dioxide**
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- ACGIH OELs - Notice of Intended Changes Listed
- Australia TWA 10 mg/m³
- Austria OEL - MAKs 5 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Denmark OEL - TWA 6 mg/m³
- Estonia OEL - TWA 5 mg/m³
- France OEL - TWA 10 mg/m³
- Greece OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 10 mg/m³
- Lithuania OEL - TWA 5 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Poland OEL - TWA 10.0 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Romania OEL - TWA 10 mg/m³
- Russia OEL - TWA 10 mg/m³
- Spain OEL - TWA 10 mg/m³
- Sweden OEL - TWAs 5 mg/m³
- Switzerland OEL -TWAs 3 mg/m³
- Vietnam OEL - TWAs 6 mg/m³
- Vietnam OEL - TWAs 5 mg/m³

**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 10 mg/m³
- Latvia OEL - TWAs 10 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Slovakia OEL - TWA 4 mg/m³
- Spain OEL - TWA 10 mg/m³
- Switzerland OEL -TWAs 3 mg/m³

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

**Exposure Controls**
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).

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

Odor: No data available.

Odor Threshold: No data available.

Molecular Formula: Mixture

Molecular Weight: Mixture

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)

FD & C Red No. 3 (E 127)

No data available

FD&C Yellow No. 6; (Sunset yellow)

No data available

Gelatin

No data available

Titanium dioxide

No data available

FD & C Blue No. 1

No data available

Disopyramide Phosphate

No data available

Lactose

No data available

Corn Starch

No data available

Talc (non-asbestiform)

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:
SAFETY DATA SHEET

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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.
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 LD 50 333-580 (F) mg/kg
  Rat Oral LD 50 333-888 (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)
11. TOXICOLOGICAL INFORMATION

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)

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
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 1, Subdivision B
Class D, Division 2, Subdivision A

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

Material Name: Disopyramide Phosphate Capsules
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Mobility in Soil: No data available
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name: Disopyramide Phosphate Capsules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date: 27-Mar-2015</td>
</tr>
<tr>
<td>Version: 4.0</td>
</tr>
</tbody>
</table>

#### 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

#### 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**: Present
- **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**: Not Listed
- **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
15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases and 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.

Toxic to Reproduction: Category 2
Xn - Harmful

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 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 27-Mar-2015
Prepared by: Product Stewardship Hazard Communication

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