



# MATERIAL SAFETY DATA SHEET

Revision date: 01-Dec-2009

Version: 2.0

Page 1 of 9

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Disopyramide Phosphate Capsules

Trade Name: Norpace  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as anti-arrhythmic

## 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  
Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.  
R60 - May impair fertility.  
R63 - Possible risk of harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification  
(NOHSC):

# MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 2 of 9  
Version: 2.0

## 2. HAZARDS IDENTIFICATION

**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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Disopyramide Phosphate	22059-60-5	244-756-1	Xn;R22 Repr.Cat.2;R60 Repr.Cat.3;R63	100 / 150 mg ***
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Gelatin	9000-70-8	232-554-6	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	Not Listed	*
FD & C Red No. 3 (E 127)	16423-68-0	240-474-8	Not Listed	*
FD & C Blue No. 1	3844-45-9	223-339-8	Not Listed	*

**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.

# MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 3 of 9  
Version: 2.0

**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.

**Disopyramide Phosphate**  
Pfizer OEL TWA-8 Hr:

250µg/m<sup>3</sup>

**Talc (non-asbestiform)**

ACGIH Threshold Limit Value (TWA)

2 mg/m<sup>3</sup> TWA

ACGIH OELs - Notice of Intended Changes

Listed

Australia TWA

2.5 mg/m<sup>3</sup> containing no asbestos fibers

Austria OEL - MAKs

Listed

Belgium OEL - TWA

Listed

Bulgaria OEL - TWA

Listed

Czech Republic OEL - TWA

Listed

Denmark OEL - TWA

Listed

Estonia OEL - TWA

Listed

Finland OEL - TWA

Listed

Greece OEL - TWA

Listed

Hungary OEL - TWA

Listed

Ireland OEL - TWAs

Listed

Netherlands OEL - TWA

Listed

## MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 4 of 9  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

<b>Analytical Method:</b>	Analytical method available for Disopyramide Phosphate. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

## MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 5 of 9  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Capsule	<b>Color:</b>	White / Orange or Brown / orange
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**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)

##### Disopyramide Phosphate

Rat Oral LD 50 333-580 (F) mg/kg  
Rat Oral LD 50 333-888 (M) mg/kg

##### 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

##### Lactose

Rat Oral LD50 > 10 g/kg

##### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

##### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 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.

## MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 6 of 9  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### 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 of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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

IARC: Group 3

#### Talc (non-asbestiform)

IARC: Group 3

#### Titanium dioxide

IARC: Group 3 (Not Classifiable)

#### FD & C Blue No. 1

IARC: Group 3

### 12. ECOLOGICAL INFORMATION

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

## MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 7 of 9  
Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** 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

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 1

**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.

**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



## MATERIAL SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules  
Revision date: 01-Dec-2009

Page 8 of 9  
Version: 2.0

### 15. REGULATORY INFORMATION

#### Disopyramide Phosphate

Australia (AICS): Listed  
EU EINECS/ELINCS List 244-756-1

#### Gelatin

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 232-554-6

#### Lactose

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 200-559-2

#### Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 238-877-9

#### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 236-675-5

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

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 220-491-7

#### FD & C Red No. 3 (E 127)

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 240-474-8

#### FD & C Blue No. 1

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 223-339-8

#### Corn Starch

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
REACH - Annex IV - Exemptions from the obligations of Register: Present  
EU EINECS/ELINCS List 232-679-6

### 16. OTHER INFORMATION

Text of R phrases mentioned in Section 3



## MATERIAL SAFETY DATA SHEET

**Material Name:** Disopyramide Phosphate Capsules  
**Revision date:** 01-Dec-2009

**Page 9 of 9**  
**Version: 2.0**

---

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and 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**