



MATERIAL SAFETY DATA SHEET

Revision date: 13-Aug-2013

Version: 3.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

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

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International CHEMTREC (24 hours): +1-703-527-3887

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 2
Toxic to Reproduction: Category 3

EU Hazard Symbols:



EU Risk Phrases:

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

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2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	%
Corn Starch	9005-25-8	232-679-6	Not Listed	*
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	*

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

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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/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	10 mg/m ³
Disopyramide Phosphate	
Pfizer OEL TWA-8 Hr:	250µg/m ³
Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	6.0 mg/m ³
	3.0 mg/m ³
Czech Republic OEL - TWA	2.0 mg/m ³
	10 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³
Greece OEL - TWA	10 mg/m ³
	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	0.8 mg/m ³
Lithuania OEL - TWA	2 mg/m ³
	1 mg/m ³
Netherlands OEL - TWA	0.25 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m ³
	1.0 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
	10 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³
	1 mg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Analytical Method:	Analytical method available for Disopyramide Phosphate. Contact Pfizer Inc for further information.
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.
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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
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11. TOXICOLOGICAL INFORMATION

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

Lactose

Rat Oral LD50 > 10 g/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

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

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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.

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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	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	232-679-6

Disopyramide Phosphate

California Proposition 65	Not Listed
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

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List 232-554-6

Lactose

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)

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

California Proposition 65 carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 236-675-5

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