



SAFETY DATA SHEET

Revision date: 22-Oct-2018

Version: 4.1

Page 1 of 11

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

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
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International CHEMTREC (24 hours): +1-703-527-3887

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

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 2 of 11
Version: 4.1



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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Disopyramide Phosphate	22059-60-5	244-756-1	Acute Tox.4 (H302) Repr.1B (H360Fd)	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	GHS 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.

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.

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 3 of 11
Version: 4.1

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

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 4 of 11
Version: 4.1

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/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
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
Romania 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
Switzerland OEL - TWAs	2 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
Latvia OEL - TWA	4 mg/m ³ 10 mg/m ³

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 5 of 11
Version: 4.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
	5 mg/m ³

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
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³

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.)

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 6 of 11
Version: 4.1

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:			
Autoignition Temperature (Solid) (°C):		No data available	
Flammability (Solids):		No data available	
Flash Point (Liquid) (°C):		No data available	
Upper Explosive Limits (Liquid) (% by Vol.):		No data available	
Lower Explosive Limits (Liquid) (% by Vol.):		No data available	

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

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 7 of 11
Version: 4.1

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 1264mg/kg

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

Rat Oral LD50 > 10,000 mg/kg
Mouse Oral LD50 > 6,000mg/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)

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

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 8 of 11
Version: 4.1

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.

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 9 of 11
Version: 4.1

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

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 10 of 11
Version: 4.1

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:	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	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:	Present
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
Pfizer Global Environment, Health, and Safety Operations

SAFETY DATA SHEET

Material Name: Disopyramide Phosphate Capsules
Revision date: 22-Oct-2018

Page 11 of 11
Version: 4.1

Pfizer Inc believes that the information contained in this 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