MATERIAL SAFETY DATA SHEET

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

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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Tikosyn (Dofetilide) capsules - 0.125 mg, 0.25 mg, 0.50 mg

Trade Name: Tikosyn®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for heart rhythm control (anti-arrhythmic)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Dofetilide	115256-11-6	Not listed	<0.5
Colloidal silicon dioxide	7631-86-9	231-545-4	*
Corn Starch	9005-25-8	232-679-6	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: 0.125 mg - Orange/white capsules 0.25 mg - Peach capsules 0.50 mg - Peach/white capsules

Signal Word: WARNING

Statement of Hazard: Potent cardiovascular drug

Additional Hazard Information:

Short Term: Dust may cause transient irritation . Active ingredient is not a skin irritant ; (based on animal data) . Active ingredient is not a skin sensitizer . Accidental ingestion may cause effects similar to those seen in clinical use. Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and the developing fetus.

Known Clinical Effects: The most frequent adverse effects seen during clinical use are headache, chest pain, and dizziness.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: No data available

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature. Protect from moisture and humidity.

Storage Temperature: 15 - 30 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Dofetilide

Pfizer OEL TWA-8 Hr:	2 ug/m^3

Colloidal silicon dioxide

OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO2) mg/m^3 TWA = 20 mppcf TWA
Australia TWA	= 2 mg/m^3 TWA

Corn Starch

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for dofetilide. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product. 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:	Capsules containing white to off-white crystalline powder	**Color:**	Orange/white (0.125 mg) Peach (0.25 mg) Peach/white (0.50 mg)
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Dofetilide
Mouse Oral LD50 > 300 mg/kg
Rat Oral LD50 > 300 mg/kg
Rat Dermal LD50 > 2000 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.
Inhalation Acute Toxicity No data available
Ingestion Acute Toxicity See Acute toxicity table

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Dofetilide
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Negative

Skin Irritation / Sensitization Dofetilide produced evidence of skin sensitization in 2 of 10 test animals and an additional two animals gave inconclusive responses. A second challenge produced no evidence of skin sensitization.
Subchronic Effects Studies of 1, 3, and 6 months have resulted in testicular atrophy and a decrease in testis weight in mice, rats, and dogs. ECG changes were seen exclusively in dogs at all dose levels.
Chronic Toxicity A one year study in rats resulted in testicular atrophy with reduced testicular weight and abnormal epididymis content at 20 mg/kg/day. A one-year study in dogs resulted in ECG changes at all dose levels (0.1, 1, and 10 mg/kg/day) and two deaths attributed to cardiac effects.
Chronic Effects/Carcinogenicity No evidence of carcinogenic potential was observed when this material was tested in mice and rats at doses up to 20 mg/kg/day for 2 years.

Reproductive Effects No evidence of impaired fertility was observed when this material was tested in rats at doses up to 4 mg/kg/day.
Teratogenicity Embryomortality was seen in mice at 2 and 5 mg/kg/day and in rats at 1 mg/kg/day. Delayed bone development (ossification) and other treatment related anomalies (syndactylia, digit agenesis, sternebral anomalies, and cleft palate), were also seen in rats and mice.
Mutagenicity No evidence of mutagenic or clastogenic activity was observed when dofetilide was tested in bacterial and mammalian cells in vivo and in vitro.

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Colloidal silicon dioxide
IARC: Group 3

At increase risk from exposure: Drugs of this class have been associated with rare, but potentially serious cardiac events. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater and degrade promptly. Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Mobility, Persistence and Degradability: The active ingredient in this formulation has a low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected.

Bioaccumulation and Toxicity: This material will not inhibit wastewater treatment microorganisms. See the aquatic toxicity data of this active ingredient in the table, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Dofetilide
Daphnia Magna NPDES LC-50 48 Hours 1.7 mg/ml
Mysid Shrimp NPDES LC-50 48 Hours 5.5 mg/L
Sheepshead Minnow LC50 > 23 mg/L
Red Algae IC50 > 1 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
WARNING
Potent cardiovascular drug

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Dofetilide

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet