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

Product Identifier

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

Trade Name: TIKOSYN

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for heart rhythm control (anti-arrhythmic)

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1B

Label Elements

Signal Word: Danger
Hazard Statements: H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
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 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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dofetilide</td>
<td>115256-11-6</td>
<td>Not Listed</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;0.5</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.1B (H360FD)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2 (H373)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 2 (H401)</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 2(H411)</td>
<td></td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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</tr>
</tbody>
</table>

Additional Information:  

* 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. |
|                                  | 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:
Use carbon dioxide, dry chemical, or water spray.

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. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Dofetilide
Pfizer OEL TWA-8 Hr: 2 µg/m³

Corn Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Concentration (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria OEL - TWA</td>
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<td>4.0</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>5</td>
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<tr>
<td>Ireland OEL - TWAs</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
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<tr>
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<tr>
<td>Australia TWA</td>
<td>10</td>
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<td>Belgium OEL - TWA</td>
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<td>Spain OEL - TWA</td>
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<td>Switzerland OEL - TWAs</td>
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<td>Vietnam OEL - TWAs</td>
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<td></td>
<td>5</td>
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<tr>
<td>Colloidal silicon dioxide</td>
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<tr>
<td>Australia TWA</td>
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<td>Austria OEL - MAKs</td>
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<td>Germany (DFG) - MAK</td>
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<td></td>
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<tr>
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<tr>
<td>Switzerland OEL - TWAs</td>
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<td>Magnesium stearate</td>
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<tr>
<td>Lithuania OEL - TWA</td>
<td>5</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Tikosyn (Dofetilide) capsules - 0.125 mg, 0.25 mg, 0.50 mg
Revision date: 30-Nov-2018
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Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 disposable gloves (e.g. Nitrile, etc.) (double 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 disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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)

Odor: No data available.

Molecular Formula: Mixture

Odor Threshold: No data available.

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)

Corn Starch
No data available

Microcrystalline cellulose
No data available

Dofetilide
Predicted 7.4 Log D 1.7

Magnesium stearate
No data available

Colloidal silicon dioxide
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
- Polymerization: Will not occur

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.

Short Term: Dust may cause transient irritation. (based on animal data). 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.

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>Species</th>
<th>LD50</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Oral</td>
<td>Rat</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbit</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Dofetilide</td>
<td>Oral</td>
<td>Rat</td>
<td>LD50</td>
<td>&gt; 300 mg/kg</td>
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<tr>
<td></td>
<td></td>
<td>Rat</td>
<td>Dermal</td>
<td>LD50</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Oral</td>
<td>Rat</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Inhalation</td>
<td>Rat</td>
<td>LC50</td>
<td>&gt; 2000 mg/m³</td>
</tr>
</tbody>
</table>

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.

Irritation / Sensitization: (Study Type, Species, Severity)
11. TOXICOLOGICAL INFORMATION

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

Dofetilide
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Negative
Skin Sensitization - GPMT  Guinea Pig  Negative
Antigenicity- Passive cutaneous anaphylaxis  Guinea Pig  Negative
Antigenicity- Active anaphylaxis  Guinea Pig  Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Dofetilide
6 Month(s)  Dog  Oral  2 mg/kg/day  NOAEL  Male reproductive system, Heart
6 Month(s)  Rat  Oral  0.5 mg/kg/day  NOAEL  Male reproductive system
3 Month(s)  Rat  Oral  10 mg/kg/day  NOAEL  Male reproductive system
1 Year(s)  Dog  Oral  0.1 mg/kg/day  NOAEL  Male reproductive system, Heart
1 Year(s)  Rat  Oral  2 mg/kg/day  NOAEL  Male reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Dofetilide
Embryo / Fetal Development  Mouse  Oral  0.5 mg/kg/day  NOAEL  Embryotoxicity
Peri-/Postnatal Development  Rat  Oral  1 mg/kg/day  NOAEL  No effects at maximum dose
Fertility and Embryonic Development  Rat  Oral  0.05 mg/kg/day  NOAEL  Developmental toxicity
Embryo / Fetal Development  Rat  Oral  0.5 mg/kg/day  NOAEL  Embryotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Dofetilide
Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
Mammalian Cell Mutagenicity  Mouse Lymphoma  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Negative
In Vivo Chromosome Aberration  Mouse Bone Marrow  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Dofetilide
24 Month(s)  Rat  Oral  10 mg/kg/day  NOAEL  Not carcinogenic
24 Month(s)  Mouse  Oral  20 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:  See below

Colloidal silicon dioxide
IARC:  Group 3 (Not Classifiable)
NTP:  Reasonably Anticipated To Be A Human Carcinogen
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.

Toxicity:

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

Dofetilide
- *Daphnia magna* (Water Flea)  NPDES LC-50 48 Hours 1.7 mg/ml
- *Mysidopsis bahia* (Mysid Shrimp) NPDES LC-50 48 Hours 5.5 mg/L
- *Cyprinodon variegatus* (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.

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Dofetilide
- Predicted 7.4  Log D  1.7

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.

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
15. REGULATORY INFORMATION

Dofetilide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

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

Microcrystalline cellulose
- 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: 232-674-9

Colloidal silicon 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: 231-545-4

Magnesium stearate
- 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: 209-150-3

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.
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 30-Nov-2018
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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