



MSN Laboratories Private Limited  
R&D Center, Formulation Division.

	<b>MATERIAL SAFETY DATA SHEET</b>	Page No 1 of 3
<b>Product Name</b>	Dofetilide Capsules 125 mcg, 250 mcg and 500 mcg	

### 1. Product Information

**Product Name:** Dofetilide Capsules 125 mcg, 250 mcg and 500 mcg

### 2. Composition/Information on Ingredients

**C.A.S. No :** : 115256-11-6  
**Molecular Formula** :  $C_{19}H_{27}N_3O_5S_2$   
**Formula Weight** : 441.56  
**Chemical Name** :  $\beta$ -[(*p*-Methanesulfonamidophenethyl)methylamino]methanesulfono-*p*-phenetidine

### 3. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

### 4. First Aid Measures

**Ingestion** If awake and able to swallow, rinse mouth with water. Never give anything by mouth if unconscious or having convulsions. Obtain medical attention.  
**Eye** Wash immediately with clean and gently flowing water for at least 15 minutes.  
**Skin** Flush exposed area with large amounts of soap and water.  
**Inhalation** If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical attention

### 5. Emergency Overview

**Major Health Hazards:** No major health hazards are known

### 6. Fire Fighting Measures

**Flammability :** Non flammable  
**Means of Extinction:** Carbon dioxide, dry chemical powder or appropriate foam. Water spray.  
**Flashpoint (°C) and Method:** Not Applicable  
**Auto ignition Temperature (°C):** Not Applicable  
**Hazardous Combustion Products [NFPA]:** Carbon dioxide, carbon monoxide, Hydrogen chloride, Hydrogen fluoride.

### 7. Accidental Release Measures

**Leak and Spill Procedures**  
Wear protective clothing and equipment before working.

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<b>MATERIAL SAFETY DATA SHEET</b>		Page No 2 of 3
<b>Product Name</b>	Dofetilide Capsules 125 mcg, 250 mcg and 500 mcg	

For large spills prevent entry into waterways, sewers and surface drainage systems.

Collect the spillage and place it in a suitable, properly labeled container and dispose the waste

In accordance with applicable local/state laws.

### 8. Handling and Storage

#### Handling Procedures and Equipment

Avoid contact with eyes, skin, and clothing.

#### Storage Requirements:

Store at controlled room temperature, 15° to 30°C (59° to 86°F). Protect from Moisture and Humidity

### 9. Exposure Controls/Personal Protection

#### Exposure Limits

Data not available

#### Specific Engineering Controls *(such as ventilation, enclosed process)*

Not applicable

#### Personal Protective Equipment

Safety glasses with side shields.

Safety gloves

Protective clothing

Chemical resistant footwear

### 10. Physical Properties

125 mcg : White to off white powder filled in Size "4" hard gelatin capsules with white opaque body imprinted with "1" with black color band and light orange opaque cap imprinted with "MD" in black ink.

250 mcg : White to off white powder filled in Size "4" hard gelatin capsules with peach opaque body imprinted with "2" with black color band and peach opaque cap imprinted with "MD" in black ink.

500 mcg : White to off white powder filled in Size "2" hard gelatin capsules with white opaque body imprinted with "3" with black color band and peach opaque cap imprinted with "MD" in black ink.

### 11. 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

**Hazardous Decomposition Products:** None known

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	<b>MATERIAL SAFETY DATA SHEET</b>	Page No 3 of 3
<b>Product Name</b>	Dofetilide Capsules 125 mcg, 250 mcg and 500 mcg	

**12. Toxicological Information**

Acute oral toxicity : Oral TDLO 7.14 mg/kg

Acute inhalation toxicity: No data available.

Acute dermal toxicity : No data available.

Skin irritation : Non-irritant (rabbit)

Eye irritation : No data available.

Reproductive toxicity : No data available.

Teratogenicity : No data available.

Aspiration hazard : No data available.

Carcinogenicity : NTP?No IARC Monographs ?No OSHA Regulated?No

**13. Ecological Information****[Aquatic Toxicity]**

No information is available about the potential of this product to produce adverse environmental affects.

**14. Disposal Considerations****Waste Disposal**

It should be taken care that rejected products/ returned goods are not resold or reused.

Local and national regulations are to be observed before disposing of this product.

**15. Transport Information****Special Shipping Information**

It has no known significant hazards requiring special packaging or labeling for shipping purpose

**16. Regulatory Information**

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

Emergency Response Guide Book: N/A

Special precautions for users: N/D

**17. Other Information**

The information and recommendations in this safety data sheet are to the best of our knowledge, accurate at the date of issue. Nothing herein shall be deemed to create any warranty expressed or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material for any particular purpose.

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