



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

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<b>Product Name</b>	Roflumilast Tablets 250 mcg	

### 1. Product Information

**Product Name:** Roflumilast Tablets 250 mcg

### 2. Composition/Information on Ingredients

**C.A.S. No :** : 162401-32-3  
**Molecular Formula** :  $C_{17}H_{14}ClF_2N_2O_3$   
**Formula Weight** : 403.22  
**Chemical name** : N-(3,5- dichloropyridin-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxy-benzamide.

### 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 :** Catches fire when it comes in contact with open flames; Emits toxic fumes under fire conditions.

**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.

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

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In accordance with applicable local/state laws.

### 8. Handling and Storage

**Handling Procedures and Equipment**

Avoid contact with eyes, skin, and clothing.

**Storage :**Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C(59° - 86°F).

[See USP Controlled Room Temperature].

### 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 and Chemical Properties

White to off white, round, flat face bevel edged, uncoated tablets, debossed with "R" on one side and "0.25" on other side.

### 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

### 12. Toxicological Information

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

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### 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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