



## **SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Roflumilast Tablets, 500 mcg
<b>Recommended use</b>	Pharmaceutical Product
<b>Manufacturer</b>	<b>Hetero Labs Limited, Unit-III</b> 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<b>Hazard statements</b>	Toxic if swallowed. Causes skin irritation Causes serious eye irritation. May cause respiratory irritation. Very toxic to aquatic life May cause long lasting harmful effects to aquatic life
<b>Precautionary statements</b>	Avoid breathing dust/fume/gas/mist/vapors/spray Wash thoroughly after handling. Do not eat, drink or smoke when using this product Use only outdoors or in a well-ventilated area. Avoid release to the environment Wear protective gloves / eye protection / face protection. If swallowed: Immediately call a poison center/doctor. Specific treatment (see on this label). Rinse mouth. If on skin: Wash with plenty of water. IF INHALED: Remove person to fresh air and keep comfortable for breathing If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Call a poison center/doctor if you feel unwell Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.



	Collect spillage Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/ container in accordance with local/regional/national/international regulations.
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredients</b>	Roflumilast
CAS	162401-32-3
<b>Section 4: First-Aid Measures</b>	
<b>After swallowing</b>	Do not induce vomiting; immediately call for medical help
<b>After inhalation</b>	In case of unconsciousness place patient stably in side position for transportation
<b>After skin contact</b>	Immediately wash with water and soap and rinse thoroughly.
<b>After eye contact</b>	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
<b>Most important symptoms and effects, both acute and delayed</b> May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects. No further relevant information available	
<b>Indication of any immediate medical attention and special treatment needed</b> No further relevant information available.	
<b>Section 5: Fire-Fighting Measures</b>	
<b>Suitable Extinguishing Media</b>	Use fire fighting measures that suit the environment. A solid water stream may be inefficient.
<b>Special hazards arising from the substance or mixture</b>	No further relevant information available.
<b>Advice for firefighters</b>	No special measures required.
<b>Protective equipment</b>	
<b>Section 6: Accidental Release Measures</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	Not required.
<b>Environmental precautions</b>	Do not allow to enter sewers/ surface or ground water
<b>Methods and materials for containment and cleaning up</b>	Dispose contaminated material as waste according to item 13. Ensure adequate ventilation



Section 7: Handling and Storage	
<b>Handling</b>	Thorough dedusting
<b>Precautions for safe handling</b>	
<b>Information about protection against explosions and fires</b>	No special measures required
<b>Conditions for safe storage, including any incompatibilities Storage</b>	
<b>Requirements to be met by storerooms and receptacles</b>	No special requirements.
<b>Information about storage in one common storage facility</b>	Not required
<b>Specific end use(s)</b>	No further relevant information available.
Section 8: Exposure Controls/Personal Protection	
<b>Additional information about design of technical systems</b>	No further data
<b>Control parameters</b>	
<b>Components with limit values that require monitoring at the workplace</b>	Not required.
<b>Additional information</b>	The lists that were valid during the creation were used as basis.
<b>Exposure controls</b>	
<b>Personal protective equipment</b>	
<b>General protective and hygienic measures</b>	
Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.	
<b>Breathing equipment</b>	
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.	
<b>Protection of hands: Protective gloves</b>	The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
<b>Material of gloves</b>	The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.



<b>Penetration time of glove material</b>	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
<b>Eye protection</b>	Tightly sealed goggles.

### Section 9: Physical and Chemical Properties

<b>Physical Form</b>	Solid								
<b>Description</b>	<p>Roflumilast tablet is supplied as white to off-white, round, flat bevel edged tablets, debossed with 'H' on one side and 'I' on the other side.</p> <p>Roflumilast tablets are available:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 70%;">Bottles of 30 Tablets</td> <td>NDC 31722-623-30</td> </tr> <tr> <td>Bottles of 90 Tablets</td> <td>NDC 31722-623-90</td> </tr> <tr> <td>Blister Card of 10 Unit-Dose tablets</td> <td>NDC 31722-623-31</td> </tr> <tr> <td>Blister Pack of 100 (10 x 10)</td> <td>NDC 31722-623-32</td> </tr> </table>	Bottles of 30 Tablets	NDC 31722-623-30	Bottles of 90 Tablets	NDC 31722-623-90	Blister Card of 10 Unit-Dose tablets	NDC 31722-623-31	Blister Pack of 100 (10 x 10)	NDC 31722-623-32
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### Section 10: Stability and Reactivity

<b>Reactivity</b>	No further relevant information available.
<b>Chemical stability</b>	
<b>Thermal decomposition / conditions to be avoided:</b>	No decomposition if used according to specifications.
<b>Possibility of Hazardous Reactions</b>	No dangerous reactions known
<b>Conditions to Avoid</b>	No further relevant information available.
<b>Incompatible materials</b>	Strong oxidizing agents
<b>Hazardous Decomposition products</b>	Carbon dioxide, carbon monoxide, hydrogen chloride gas, hydrogen fluoride, nitrogen oxides

### Section 11: Toxicological Information

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

### Section 12: Ecological Information

**Toxicity**

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available

**Ecotoxicological effects:**

- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

Very toxic for aquatic organisms

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### Section 13: Disposal Considerations

**Waste treatment methods**

- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging's:**
- **Recommendation:** Disposal must be made according to official regulations

### Section 14: Transport Information

<b>UN-Number</b>	UN2811
· <b>DOT, IMDG, IATA</b>	
<b>UN proper shipping name</b>	
- DOT	Toxic solids, organic, no's.(Roflumilast)
- IMDG	Toxic solid, organic, no's. (Roflumilast)
- IATA	Toxic solid, organic, no's. (Roflumilast)
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
<b>UN "Model Regulation":</b>	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (ROFLUMILAST), 6.1, III, ENVIRONMENTALLY HAZARDOUS

### Section 15: Regulatory Information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further relevant information available.

- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.



- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
  - **TSCA (Toxic Substances Control Act):** Substance is not listed.
  - **Hazardous Air Pollutants** Substance is not listed.
  - **Proposition 65**
  - **Chemicals known to cause cancer:** Substance is not listed.
  - **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
  - **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
  - **Chemicals known to cause developmental toxicity:** Substance is not listed.
  - **Carcinogenic categories**
  - **EPA (Environmental Protection Agency)** Substance is not listed.
  - **TLV (Threshold Limit Value)** Substance is not listed.
  - **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed
- Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

#### Section 16: Other Information

**Issue Date : 08-10-2022**

**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

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

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