



## **SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	<b>Fingolimod Capsules 0.5 mg</b>
<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>Classification:</b>	
Skin	Causes skin irritation.
Eye	Causes serious eye irritation
STOT SE 3	May cause respiratory irritation
Aquatic Acute 3	Harmful to aquatic life.
Aquatic Chronic 3	Harmful to aquatic life with long lasting effects
<b>GHS label elements</b>	The substance is classified and labeled according to the Globally Harmonized System (GHS).
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredients</b>	Fingolimod
CAS	162359-55-9
<b>Section 4: First-Aid Measures</b>	
<b>After swallowing</b>	If symptoms persist consult doctor
<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>Section 5: Fire-Fighting Measures</b>	



<b>Suitable Extinguishing agents</b>	Use fire fighting measures that suit the environment. A solid water stream may be inefficient.
<b>Specific hazards arising from the substance or mixture</b>	No further relevant information available.
<b>Protective equipment</b>	No special measures required.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal precautions</b>	Not required.
<b>Environmental Precautions</b>	Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water.
<b>Methods and materials for containment and cleaning up</b>	Ensure adequate ventilation
<b>Protective Action Criteria for Chemicals</b> · PAC-1: Substance is not listed. · PAC-2: Substance is not listed. · PAC-3: Substance is not listed.	
<b>Section 7: Handling and Storage</b>	
<b>Handling:</b> · Precautions for safe handling	No special precautions are necessary if used correctly. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure. Keep away from sources of ignition. Take precautionary measures against static discharge.
<b>Information about protection against explosions and fires</b>	No special measures required
<b>Conditions for safe storage, including any incompatibilities</b>	Store in accordance with information listed on the product insert.
<b>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>Further information about storage conditions</b>	Keep receptacle tightly sealed.
<b>Specific end use(s)</b>	No further relevant information available
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Additional information about</b>	No further data

<b>design of technical systems</b>	
<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>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</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>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	Solid
<b>Description</b>	Fingolimod Capsules 0.5 mg are bright yellow cap / opaque white body size '4' hard gelatine capsule imprinted with 'H' on cap with black ink and 'F7' on body with blue ink, filled with white to off white powder.  Bottle of 30s NDC 31722-889-30 Blister Card of 10s NDC 31722-889-31 Blister Carton of 100s (10x10s) NDC 31722-889-32
<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity</b>	No further relevant information available



<b>Chemical stability</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, nitrogen oxides

### Section 11: Toxicological Information

#### Information on toxicological effects

- **Acute toxicity:**
- **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

<b>Toxicity</b>	No further relevant information available.
<b>Persistence and Degradability</b>	No further relevant information available.
<b>Bioaccumulative Potential</b>	No further relevant information available.
<b>Mobility in Soil</b>	No further relevant information available.

#### Additional ecological information:

##### General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water  
 Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.  
 Harmful to aquatic organisms

### Section 13: Disposal Considerations

<b>Waste treatment methods</b>	Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
<b>Uncleaned packagings Recommendation</b>	Disposal must be made according to official regulations

### Section 14: Transport Information

<b>UN-Number</b> · DOT, IMDG, IATA	not regulated
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<b>UN proper shipping name</b> · DOT, IMDG, IATA	not regulated
<b>Transport hazard class(es)</b> · DOT, ADN, IMDG, IATA · Class	not regulated
<b>Packing group</b> · DOT, IMDG, IATA	not regulated
<b>Environmental hazards:</b>	Not applicable.
<b>Special precautions for user</b>	Not applicable
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
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<b>UN "Model Regulation":</b>	not regulated

### 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 : 01-10-2022**

**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

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