

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Tavaborole Topical Solution 5%</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Pithampur (M.P.) – 454 775 India
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

### Section 2: Hazard(s) Identification

#### Section 2, Hazard(s) identification

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	None
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Tavaborole	174671-46-6

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

<b>Ingestion</b>	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.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

## NOTES TO HEALTH PROFESSIONALS

**Medical Treatment** Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

**OVERDOSAGE** Not Reported

## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

**Fire and Explosion Hazards** Assume that this product is capable of sustaining combustion.

**Extinguishing Media** Water spray, carbon dioxide, dry chemical powder or appropriate foam.

**Special Firefighting Procedures** For single units (packages): No special requirements needed.  
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

**Hazardous Combustion Products** Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

**Personal Precautions** Wear suitable protective clothing, gloves and eye/face protection.

**Environmental Precautions** Avoid release to the environment.

**Clean-up Methods** Collect and place it in a suitable, properly labeled container for recovery or disposal.

## Section 7: Handling and Storage

### Section 7, Handling and storage

**Handling** No special control measures required for the normal handling of this product.  
Normal room ventilation is expected to be adequate for routine handling of this product.

**Storage** Store at 20 to 25°C (68 to 77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].  
  
CAUTION: Flammable. Keep away from heat and flame.  
Discard product within 3 months after insertion of the dropper.  
Keep bottle tightly closed. Keep out of reach of children.

## Section 8: Exposure Controls/Personal Protection

### Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## Section 9: Physical and Chemical Properties

### Section 9, Physical and chemical properties

#### Physical Form

Tavaborole topical solution, 5% is clear, colorless alcohol-based solution free from foreign and visible particles packed in amber glass bottle with screw cap. At initial use, the screw cap is replaced with the dropper assembly.

Tavaborole topical solution, 5% is supplied in the following presentation:

NDC 68180-958-02: One 10 mL bottle containing 10 mL of solution with one glass pointed-tip dropper.

#### 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

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

In an oral carcinogenicity study in Sprague-Dawley rats, oral doses of 12.5, 25, and 50 mg/kg/day tavaborole were administered to rats once daily for 104 weeks. No drug related neoplastic findings were noted at oral doses up to 50 mg/kg/day tavaborole (14 times the MRHD based on AUC comparisons).

In a dermal carcinogenicity study in CD-1 mice, topical doses of 5%, 10%, and 15% tavaborole solution were administered to mice once daily for 104 weeks. No drug related neoplastic findings were noted at topical doses up to 15% tavaborole solution (89 times the MRHD based on AUC comparisons).

Tavaborole revealed no evidence of mutagenic or clastogenic potential based on the results of two in vitro genotoxicity tests (Ames assay and Human lymphocyte chromosomal aberration assay) and one in vivo genotoxicity test (rat micronucleus assay).

No effects on fertility were observed in male and female rats that were administered oral doses up to 300 mg/kg/day tavaborole (107 times the MRHD based on AUC comparisons) prior to and during early pregnancy.

## Section 12: Ecological Information

### Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## Section 14: Transport Information

### Section 14: Transport Information

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

<b>UN number</b>	UN 1170
<b>UN proper shipping name</b>	Ethanol solution
<b>Transport hazard class</b>	3
<b>Packing group</b>	II

## Section 15: Regulatory Information

### Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

### Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

**Lupin** shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.