

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

<b>Product Name</b>	<b>RIVAROXABAN FOR ORAL SUSPENSION</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Chhatrapati Sambhajinagar - 431 210 India
<b>Distributor</b>	<b>Lupin Pharmaceuticals, Inc.</b> Naples FL, 34108 United States.
<b>Identified uses of the substance or mixture</b>	Pharmaceutical

### Section 2: Hazard(s) Identification

<b>Health</b>	May cause damage to organs through prolonged or repeated exposure. Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
<b>Environment</b>	No Data is available.
<b>Precautionary statements</b>	Get medical advice/ attention if you feel unwell.

### Section 3: Composition/Information on Ingredients

<b>Ingredients</b>	<b>CAS No.</b>	<b>Ingredients</b>	<b>CAS No.</b>
Rivaroxaban IH	366789-02-8	Sodium benzoate NF	532-32-1
Mannitol USP	69-65-8	Xanthan gum NF	11138-66-2
Citric acid, anhydrous USP	77-92-9	Hydroxypropyl Methyl Cellulose NF	9004-65-3
Sucralose NF	56038-13-2	Purified Water USP	7732-18-5
Microcrystalline cellulose	9004-34-6	Carboxymethyl cellulose sodium USP	9004-32-4

\* The exact percentage composition of this mixture has been withheld as a trade secret.

### Section 4: First-Aid Measures

<b>General advice</b>	Immediate medical attention is required.
<b>Protection of first aiders</b>	First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.
<b>Inhaled</b>	After inhalation: fresh air. Consult a doctor if the person is feeling unwell.

<b>Skin contact</b>	In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.
<b>Eye contact</b>	After eye contact: rinse out with plenty of water. Remove contact lenses.
<b>If swallowed</b>	After swallowing: immediately make victim drink water (two glasses at most). Consult a physician. Please refer to the product information insert.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Special Firefighting Procedures</b>	In the event of fire, wear a self-contained breathing apparatus.
<b>Hazardous Combustion Products</b>	No information is available.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal Precautions</b>	In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Evacuate personnel to safe areas. It should not be released into the environment.
<b>Environmental Precautions</b>	
<b>Clean-up Methods</b>	Sweep up into a suitable labeled container for disposal.
<b>Section 7: Handling and Storage</b>	
<b>Handling</b>	Keep out of the reach of children. Keep away from heat and sources of ignition. Avoid inhalation, ingestion, contact with skin, and eyes.  Do not freeze.
<b>Storage</b>	Store at room temperature between 20°C and 25°C (68°F and 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Engineering Measures/Controls:</b>	All personal protective equipment should be based on a risk assessment. Consult an environmental health Safety expert if necessary. If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
<b>Personal Protective Equipment:</b>	Respiratory: Respiratory protection is generally not needed during routine conditions. Eye/Face: When handling very small quantities of the material eye protection may not be required.

Skin/Body: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product.

## Section 9: Physical and Chemical Properties

### HOW SUPPLIED

Rivaroxaban for oral suspension is available in the strengths and packages listed below:  
NDC 70748-355-01 Supplied as white to off-white granules in a translucent HDPE bottle containing 155 mg rivaroxaban, packaged with two oral dosing syringes. After reconstitution with 150 mL of purified water, 1 mL of suspension contains 1 mg rivaroxaban.

## Section 10: Stability and Reactivity

### Stability

The product is chemically stable under standard ambient conditions (room temperature).

### Reactivity

None reasonably foreseeable.

### Hazardous reactions

No dangerous reaction known under conditions of normal use.

### Conditions to avoid

To avoid thermal decomposition, do not overheat. Heat, flames, and sparks.

### Hazardous decomposition products

None.

## Section 11: Toxicological Information

### Acute toxicity

Acute oral toxicity

No data available

Acute inhalation toxicity

No data available

Acute inhalation toxicity

No data available

### Inhalation

No data available

### Skin Contact

No data available

### Ingestion

No data available

### Eye Contact

No data available

### Carcinogenicity

No data available

### Reproduction toxicity

No data available.

## Section 12: Ecological Information

<b>Ecotoxicity</b>	None Identified
<b>Hazardous reactions</b>	Product is considered stable.
<b>Conditions to avoid</b>	To avoid thermal decomposition, do not overheat, flames and sparks.
<b>Hazardous decomposition products</b>	None Known.

### Section 13: Disposal Considerations

Dispose of contents/containers in accordance with local regulations.

### Section 14: Transport Information

#### **IATA/ICAO - Not Regulated**

IATA Proper Shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

#### **IMDG - Not Regulated**

IMDG Proper Shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

#### **DOT - Not Regulated**

DOT Proper Shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

### Section 15: Regulatory Information

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

### 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.