LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Raltegravir Tablets**
Manufacturer	**Lupin Limited** Nagpur - 441108 Maharashtra, India
Manufactured for	**Lupin Pharmaceuticals, Inc.** Naples, FL 34108 United States

Section 2: Hazard(s) Identification

Health	Information on the absorption of this product via inhalation or skin contact is not available. Please refer to the product information insert.
Environment	No information is available about the potential of this product to produce adverse environmental effects. Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Ingredients	CAS
Raltegravir	871038-72-1
Microcrystalline Cellulose	9004-34-6
Povidone	25655-41-8
Croscarmellose cellulose Ph Ur	74811-65-7
Magnesium Stearate	557-04-0
Tartaric Acid	87-69-4
Opadry yellow	117698-04-1

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

Section 4: First-Aid Measures

Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs
Eye Contact	Flush eyes with plenty of water. Get medical attention.

Section 5: Fire-Fighting Measures

Flammability	Details are not available
Extinguishing Media	Use extinguishing media suitable for the surrounding area.
Special Firefighting Procedures	No further relevant information available.
Hazardous Combustion Products	Carbon oxides. Hydrogen chloride.

Section 6: Accidental Release Measures

Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
Environmental Precautions	Should not be released into the environment.
Clean-up Methods	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Handling	No special control measures are required for the normal handling of this product. 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.
Storage	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). see USP Controlled Room Temperature. Store in the original package with the bottle tightly closed.

Section 8: Exposure Controls/Personal Protection

Personal Protection	Avoid all unnecessary exposure. Wear appropriate clothing to avoid skin contact. Wash your hands and arms thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice
Appropriate engineering controls	Work must be done with effective mechanical ventilation.

Section 9: Physical and Chemical Properties

How Supplied	Raltegravir tablets USP, 600 mg are Yellow, modified capsule shaped, biconvex, film-coated tablets debossed with “LU” on one side and “J04” on the other side. They are supplied as follows: **NDC 70748-327-07** unit-of-use bottles of 60.

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Raltegravir ;	
Acute & oral toxicity	LD50 (Mouse, male and female): > 2,000 mg/kg
Inhalation	NO
Ingestion	NO
Skin Contact	NO
Mutagenicity	NO
Reproductivity:	NO
Respiratory or Skin Sensitization	NO

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Waste Disposal:
Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A (Not Regulated)
IATA UN/ID No	:	N/A (Not Regulated)
IATA Hazard Class	:	N/A (Not Regulated)
IATA Packaging Group	:	N/A (Not Regulated)
IATA Label	:	N/A (Not Regulated)

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A (Not Regulated)
IMDG UN/ID No	:	N/A (Not Regulated)
IMDG Hazard Class	:	N/A (Not Regulated)
IMDG Flash Point	:	N/A (Not Regulated)
IMDG Label	:	N/A (Not Regulated)

DOT - Not Regulated

DOT Proper shipping Name	:	N/A (Not Regulated)
DOT UN/ID No	:	N/A (Not Regulated)
DOT Hazard Class	:	N/A (Not Regulated)
DOT Flash Point	:	N/A (Not Regulated)
DOT Packing Group	:	N/A (Not Regulated)
DOT Label	:	N/A (Not Regulated)

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 MSDS.