LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Ganirelix Acetate Injection**
Manufacturer	**Lupin Limited** Nagpur - 441108 Maharashtra, India
Distributor	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
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Classification

Danger	No known significant effects.
Physical Hazard	No known significant effects

Section 3: Composition/Information on Ingredients

Name	CAS No.
Ganirelix Acetate	129311-55-3
Mannitol	123897-58-5
Glacial Acetic Acid	64-19-7
Sodium Hydroxide	1310-73-2

* Ganirelix Acetate Injection contains Ganirelix Acetate 250 mcg/0.5ml single dose

Section 4: First-Aid Measures

Inhalation	Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Skin Contact	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse.
Ingestion	Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.
Note to physicians	Treat supportively and symptomatically.

Section 5: Fire-Fighting Measures

Suitable extinguishing media	Water spray, fog, CO2, dry chemical, or alcohol resistant foam. Use water delivered as a fine spray to control fire and cool adjacent area.
Advise for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Cool fire exposed containers with water spray from a protected location.
Hazardous combustion products	Emits toxic fumes under fire conditions.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Environmental precautions	Do not release into the environment
Methods and material for containment and cleaning up	Small Liquid Spills: Absorb up with sand or other non-combustible absorbent material. Large quantities should not be discharged into the drain but removed with absorbing material. Control personal contact with the substance by using protective equipment.
Disposal Methods	Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Precautions for safe handling	Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Do not get in eyes, on skin, on clothing. Wash thoroughly after handling. Protect from light. Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers Avoid contamination of water, foodstuffs, feed or seed.

Section 8: Exposure Controls/Personal Protection

Protective Measures	Observe occupational exposure limits and minimize the risk of inhalation of vapors and mist. No open handling permitted. Closed systems are required to control at source (e.g., glove boxes/isolators). Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.
Respiratory Protection	Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed. Use redundant respiratory protection as a prudent practice for adjunct protection in addition to effective engineering controls. Powered air filter respirator. Use a positive pressure, air supplied.
Hands Protection	Chemical resistant gloves. Consider double gloving
Eyes	Wear safety glasses or goggles if eye contact is possible.
Skin & Body Protection	Additional body garments should be used based upon the task being performed (e.g., sleeveless, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate disgowning techniques to remove potentially contaminated clothing.
Hygiene Measures	Wash skin thoroughly with soap and water.

Section 9: Physical and Chemical Properties

HOW SUPPLIED	Ganirelix Acetate Injection: Supplied as a as a colorless, sterile, ready-to-use, aqueous solution intended for SUBCUTANEOUS administration only. Disposable, ready for use, single dose, sterile, prefilled 1 mL glass syringes containing 250 mcg/0.5 mL aqueous solution of ganirelix acetate closed with a rubber piston that does not contain latex.
Appearance	Liquid Injection
Odour	Not available
pH	pH- 5.0
Odour threshold	Not available
Melting point/Freezing Point	0 °C
Boiling point	100 °C
Flash point	Not available
Evaporation rate	Not available
Flammability (solid, gas)	Not available
Flammability Limit in Air	Not available
Explosive properties	Not available
Explosive properties	Not available
Oxidising properties	Not available
Vapour pressure	23 hPa (20 °C)
Vapour density	Not available
Specific Gravity	Not available
Water solubility	Miscible with water
Solubility in other solvent	Not available

Partition coefficient	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity, kinematic	Not available
Viscosity, dynamic	Not available
Upper flammability limit	Not available
Lower flammability limit	Not available

Section 10: Stability and Reactivity

Reactivity	Stable
Chemical stability	Stable under normal conditions of use
Possibility of hazardous reactions	Stable.
Condition to avoid Incompatible Material	None at ambient temperatures.
Hazardous decomposition products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

Section 11: Toxicological Information

The toxicological properties of this material have not been fully investigated.

Section 12: Ecological Information

The environmental hazards and fate of this material have not been characterized.

Ecotoxicity

Acute toxicity(Fish):	No data available.
Chronic Toxicity(Fish):	No data available.
Acute toxicity(Aquatic invertebrates):	No data available.
Chronic Toxicity(Aquatic invertebrates):	No data available.
Acute toxicity(Aquatic plants):	No data available.
Persistence and degradability:	No data available.
Bio accumulative potential:	No data available.
Mobility:	No data available

Section 13: Disposal Considerations

Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

Measures for Avoidance and Recovery:

Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway, or ground. Operations that involve the crushing or shredding of waste materials or returned goods should consider recommended exposure limits where they exist.

Section 14: Transport Information

DOT :	Not regulated.
IMDG:	International Maritime Dangerous Goods Code Not regulated.
IATA -	International Air Transport Association Not regulated.

Section 15: Regulatory Information

CERCLA Hazardous Substance List (40 CFR 302.4): None
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None
Section 313 Toxic Release Inventory (40 CFR 372): None present, or none present in regulated quantities.

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.