LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Product Name	**Sugammadex Injection**.
Manufacturer	**Lupin Limited** Nagpur 441 108 India
Manufactured for	**Lupin Pharmaceuticals, Inc.** Naples, FL 34108 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Fire & Explosion	None known.
Health	Please read the product information leaflet before use. Known hypersensitive.

Section 3: Composition/Information on Ingredients

Ingredients	CAS
Sugammadex sodium equivalent to Sugammadex base IH	343306-79-6
Hydrochloric Acid NF	7647-01-0
Sodium Hydroxide NF	1310-73-2
Water for Injection USP	7732-18-5
Nitrogen gas (N2) NF	7727-37-9

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

Section 4: First-Aid Measures

Ingestion	If swallowed, do not induce vomiting. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness. Seek medical advice.
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

Extinguishing Media	Use extinguishing media suitable for the surrounding area.
Special Firefighting Procedures	Wear breathing apparatus plus protective gloves in the event of a fire.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment.	Wear suitable protective clothing, gloves and eye/face protection.
Environmental Precautions	Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling	Handle in accordance with good industrial hygiene and safety practice. Store in a cool, dry area protected from environmental extremes. Protect from light. When not protected from light, the vial should be used within 5 days. Keep away from children.
Storage	Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F).

Section 8: Exposure Controls/Personal Protection

Personal Protection	Wear suitable protective clothing, Wear appropriate clothing to avoid skin contact. Wear gloves and eye/face protection. Avoid all unnecessary exposure. 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	Sugammadex injection is a clear and colorless to slightly brown solution intended for intravenous infusion. Sugammadex injection is available in the following presentations: Sugammadex injection 2-mL single-dose vials containing 200 mg sugammadex (100 mg/mL) Box of 10 NDC 70748-370-02. Sugammadex injection 5-mL single-dose vials containing 500 mg sugammadex (100 mg/mL) Box of 10 NDC 70748-371-02.

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Occupational Exposure Limit of sugammadex (at 8h TWA) is recommended to be 200 µg/m3.

Acute Toxicity	In adult rat bone toxicity studies, a single dose of sugammadex at 2000 mg/kg (approximately 24 times the maximum recommended human dose (MRHD) of 16 mg/kg by AUC comparison) administered to adult rats caused a slight increase in bone resorption, but had no effect on teeth color. No adverse bone effects were seen following a single dose of sugammadex at 500 mg/kg (4 times the MRHD dose of 16 mg/kg based on plasma AUC comparison).
Carcinogenic categories	Long-term animal studies to evaluate the carcinogenic potential of sugammadex have not been conducted.
Mutagenicity	Sugammadex and its mono OH-derivative tested negatively in in-vitro bacterial reverse mutation assays (Ames test), in-vitro chromosomal aberration assays in human peripheral blood lymphocytes, and in-vivo micronucleus assays in mice and rats.
Reproductivity:	Not classified based on available information.
Respiratory or Skin Sensitization	Unknown
Skin Irritation/Corrosion	Not classified based on available information.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Follow all federal, state, and local environmental 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 MSDS.