

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

<b>Product Name</b>	<b>Liraglutide Injection</b> <b>6 mg/ml</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Nagpur - 441108 Maharashtra, India
<b>Manufactured for</b>	<b>Lupin Pharmaceuticals, Inc.</b> Naples, FL 34108 United States
<b>Use of the Substance/mixture</b>	Pharmaceuticals

### Section 2: Hazard(s) Identification

<b>Health</b>	Please refer to the product information insert. May be harmful if swallowed. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulty if inhaled.
<b>Physical Hazard</b>	Obtain special instructions before use
<b>Fire and Explosion</b>	Expected to be non-combustible

### Section 3: Composition/Information on Ingredients

Ingredients	CAS No.
Liraglutide	204656-20-2
Propylene Glycol USP	57-55-6
Disodium Hydrogen Phosphate Dihydrated USP	10028-24-7
Phenol USP	108-95-2
Sodium Hydroxide	1310-73-2
Hydrochloric acid	7647-01-0
Water for Injection USP	7732-18-5
Nitrogen gas	7727-37-9

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

### Section 4: First-Aid Measures

<b>General advice</b>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<b>Eye contact</b>	Wash out immediately with water. If irritation continues, seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
<b>Skin Contact</b>	If skin or hair contact occurs: Immediately remove all contaminated clothing, including footwear Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

<b>Inhalation</b>	If fumes, aerosols or combustion product are inhaled remove from contaminated areas. Other measures are usually unnecessary.
<b>Ingestion</b>	Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.
<b>Note to physicians</b>	Treat symptomatically.

## Section 5: Fire-Fighting Measures

<b>Suitable extinguishing media</b>	Alert the Fire Brigade and tell them the location and nature of the hazard. Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control the fire and cool the adjacent area.
<b>Advice for firefighters</b>	Positive-pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection
<b>Hazardous combustion products</b>	During combustion, it may emit irritant fumes.

## Section 6: Accidental Release Measures

<b>Personal precautions, protective equipment, and emergency procedures</b>	Wear suitable protective clothing, gloves, and eye/face protection.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses, or onto the ground.
<b>Methods and materials for containment and cleaning up</b>	Contain the source of the spill if it is safe to do so. Do not touch or walk through spilled material. Absorb spillage to prevent material damage.
<b>Disposal Methods</b>	Dispose of in accordance with local, state, and national regulations.

## Section 7: Handling and Storage

<b>Precautions for safe handling</b>	Avoid inhalation, contact with eyes, and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.
<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practices.
<b>Conditions for safe storage, including any incompatibilities</b>	
<b>Storage conditions</b>	<p>Prior to first use, liraglutide injection should be stored in a refrigerator between 36°F to 46°F (2°C to 8°C). Do not store in the freezer or directly adjacent to the refrigerator cooling element.</p> <p>Do not freeze liraglutide injection, and do not use liraglutide injection if it has been frozen.</p> <p>After first use of the liraglutide injection pen, the pen can be stored for 30 days at controlled room temperature (59°F to 86°F; 15°C to 30°C) or in a refrigerator (36°F to 46°F; 2°C to 8°C).</p> <p>Keep the pen cap on when not in use.</p> <p>Protect liraglutide injection from excessive heat and sunlight.</p> <p>Always remove and safely discard the needle after each injection and store the liraglutide injection pen without an injection needle attached.</p> <p>This will reduce the potential for contamination, infection, and leakage while also ensuring dosing accuracy.</p> <p>Always use a new needle for each injection to prevent contamination.</p>

## Section 8: Exposure Controls/Personal Protection

<b>Personal protection</b>	Avoid all unnecessary exposure.
<b>Appropriate engineering controls</b>	Work must be done with effective mechanical ventilation. There must be access to running water and eye wash.
<b>Individual protection measures, such as personal protective equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands</b>	Polyvinylchloride/ Nitrile rubber gloves
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin</b>	Impervious protective clothing is recommended if skin contact with drug products is possible and for bulk processing operations.
<b>Respiratory protection</b>	Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

## Section 9: Physical and Chemical Properties

<b>HOW SUPPLIED</b>	Liraglutide Injection: 18 mg/3 mL (6 mg/mL) clear, colorless solution in a pre-filled, single-patient-use pen that delivers doses of 0.6 mg, 1.2 mg, or 1.8 mg is available in the following package sizes: 2 x Liraglutide Injection Pen NDC 70748-346-02 3 x Liraglutide Injection Pen NDC 70748-346-03
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## Section 10: Stability and Reactivity

<b>Reactivity</b>	Not reactive under normal use and conditions. Avoid reaction with oxidizing agent.
<b>Chemical stability</b>	Product is considered stable
<b>Possibility of hazardous reactions</b>	The product is considered stable. Hazardous polymerization will not occur. None known.
<b>Incompatible materials</b>	Keep away from strong oxidizers, excessive heat and sunlight.
<b>Hazardous decomposition products</b>	No known hazardous decomposition products.

## Section 11: Toxicological Information

**Acute toxicity :** Single dose studies were performed in mice and rats in standard design studies and in monkeys in a maximum tolerated dose (MTD) study. A single dose of 10 mg/kg was generally well tolerated by mice and rats without mortality. In monkeys, a single SC administration of 5 mg/kg was well tolerated without mortality. The observed reductions in body weight and food consumption can be regarded as pharmacologically mediated.

Chemical Name	Oral LD50.	Dermal LD50	Inhalation LC50	Intravenous LD50
Liraglutide	-	-	-	-
Phenol	317 mg/kg[2] (Rat)	850 mg/kg[2] (rabbit)	0.177 mg/L4h[2] (mouse)	-

### Information on toxicological effects

#### Acute toxicity:

##### · Primary irritant effect:

· **On the skin:** There is sufficient evidence to classify this material as skin corrosive or irritating.

- **On the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Interactive effects** No interactive effects between components are known.

#### **Carcinogenic categories**

- **IARC** (International Agency for Research on Cancer) Substance is not listed.
- **NTP** (National Toxicology Program) Substance is not listed.
- **OSHA-Ca** (Occupational Safety & Health Administration) Substance is not listed.
- **NIOSH** (National Institute for Occupational Safety and Health) Substance is not listed.
- **Alternative sources for toxicological information** - NA

## **Section 12: Ecological Information**

#### **Toxicity**

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
Phenol	LOW (Half-life = 10 days)	LOW (Half-life = 0.95 days)
- **Bio accumulative potential**

Ingredient	Bioaccumulation
Phenol	LOW (BCF = 17.5)
- **Mobility in soil**

Ingredient	Mobility
Phenol	LOW (Log KOC = 268)
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## **Section 13: Disposal Considerations**

Incinerate in an approved facility. 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

### 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.