LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Identification

Material	**Sildenafil for Oral Suspension 10 mg/mL**
Manufacturer	**Lupin Limited** Goa - 403 722 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

Section 2: Hazard(s) Identification

Hazard(s) identification

Classification	Not classified as hazardous.
Physical Hazard	Combustible Dust May form combustible dust concentrations in air

Section 3: Composition/Information on Ingredients

Composition/information on ingredients

Ingredients	**CAS**
Sildenafil Citrate USP	171599-83-0

Section 4: First-Aid Measures

First-aid measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists
Skin Contact	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Use Soap. Obtain medical attention if skin reaction occurs.
Inhalation	In case of accidental ingestion, wash out mouth with copious amounts of water. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Seek medical attention immediately.
Note to physicians	None.

Section 5: Fire-Fighting Measures

Fire-fighting measures

Suitable Extinguishing Media	Use carbon dioxide, extinguishing powder, foam, or water
Advise for fire fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.

Section 6: Accidental Release Measures

Accidental release measures

Personal precautions, protective equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. 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 ccordance with applicable laws and good laboratory practices. Wash and dry hands.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and materials for containment and cleaning up	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Disposal Methods	Dispose of in accordance with local, state, and national regulations. If possible, return the pharmaceutical to the manufacturer for proper disposal being careful to properly label and securely package the material.

Section 7: Handling and Storage

Handling and storage

Precautions for safe handling	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.
Storage	**Constituted Oral Suspension** Store below 30°C (86°F) or in refrigerator at 2° to 8°C (36° to 46°F). Do not freeze. The shelf-life of the constituted oral suspension is 60 days. Any remaining oral suspension should be discarded 60 days after constitution.

Section 8: Exposure Controls/Personal Protection

Exposure controls/personal protection

Use appropriate personal protective equipment for protection.

Appropriate engineering controls	Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Individual protection measures, such as personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes	Wear safety glasses or goggles if eye contact is possible. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Skin	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL

Section 9: Physical and Chemical Properties

Physical and chemical properties

Physical Form

Sildenafil powder for oral suspension is supplied in amber glass bottles. Each bottle contains white to light yellow colored granular powder containing 1.57 g of sildenafil citrate (equivalent to 1.12 g sildenafil). Following constitution, the volume of the oral suspension is 112 mL (10 mg sildenafil/mL). A 2 mL oral dosing syringe (with 0.5 mL and 2 mL dose markings) and a press-in bottle adaptor are also provided.

Sildenafil Powder for Oral Suspension		
Package Configuration	Strength	NDC
Powder for oral suspension - bottle	10 mg/mL (when reconstituted)	68180-283-01

Appearance	Powder
Odor	Not available
Odor threshold	Not available
Melting point/freezing point	Not available
Boiling point / boiling range	Not available.
Flash point	Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not available
Flammability Limit in Air	Not available.
Upper flammability limit	Not available
Lower flammability limit	Not available
Vapor pressure	Not available.
Vapor density	Not available.
Specific Gravity	Not available
Water solubility	Not available
Solubility in other solvent	Not available
Partition coefficient	Not available
Auto ignition temperature	Not available
Decomposition temperature	Not available
Kinematic viscosity	Not available
Dynamic viscosity	Not available
Explosive properties	Not available
Oxidizing properties	Not available

Section 10: Stability and Reactivity

Stability and reactivity

Reactivity	No data available
Chemical stability	Stable under normal conditions of use
Possibility of Hazardous Reactions	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products	No data available.

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Section 11: Toxicological Information

Toxicological information

Acute toxicity

Chemical Name	Oral LDmin.	Dermal LD50	Inhalation LC50	Intravenous LD50
Sildenafil citrate	300-500 mg/kg (Rat)	> 2000 mg/kg (Rat)	-	-

Information on toxicological effects	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	May be harmful if swallowed. May cause eye irritation (based on components).
Long Term:	Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

Known Clinical Effects:	Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color vision, effects on hearing, and effects on vision.

Section 12: Ecological Information

Ecological Information

In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

Eco toxicity	Not available.
Persistence and degradability	Not available.
Bioaccumulation	Not available.
Mobility	Not available.
Other adverse effects	Not available.

Section 13: Disposal Considerations

Disposal Considerations

Disposal of wastes: Disposal should be in accordance with applicable regional, national and local laws and regulations.

Section 14: Transport Information

Transport Information

Not Regulated
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Section 15: Regulatory Information

Regulatory Information

NA

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.