

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Identification

Material	Paliperidone Extended-Release Tablets 1.5 mg, 3 mg, 6 mg and 9 mg
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
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Hazard(s) identification

Classification

Danger

Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation or skin absorption.
May cause eye, skin, or respiratory system irritation.
Toxic if swallowed.

Physical Hazard

Combustible Dust
May form combustible dust concentrations in air.

Section 3: Composition/Information on Ingredients

Drug Substance: Paliperidone

Name	CAS No.	Quantity in 1.5 mg Tablet	Quantity in 3 mg Tablet	Quantity in 6 mg Tablet	Quantity in 9 mg Tablet
Paliperidone	144598-75-4	1.5 mg	3.0 mg	6.0 mg	9.0 mg

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	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion	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	Treat symptomatically

Section 5: Fire-Fighting Measures

Fire-fighting measures

Suitable extinguishing media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Advise for fire fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous combustion products	Hydrogen fluoride. Carbon oxides. Nitrogen oxides (NOx). Phosgene.

Section 6: Accidental Release Measures

Accidental release measures

Personal precautions, protective equipment and emergency procedures	<p>Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. Avoid raising and breathing dust, and provide adequate ventilation.</p> <p>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.</p>
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and material containment and cleaning up	<p>for 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.</p> <p>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</p>
Disposal Methods	Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Handling and storage

Precautions for safe handling	<p>Minimize dust generation and accumulation. Avoid breathing dust. Avoid prolonged or repeated exposure.</p> <p>Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE.</p>
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Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases.

Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice

Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed. Store as directed by product packaging.

Storage

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture. Keep out of reach of children.

Section 8: Exposure Controls/Personal Protection

Exposure controls/personal protection

Personal protection

Use appropriate personal protective equipment for protection.

Appropriate 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.

Skin

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection

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

Information on basic physical and chemical properties

Appearance

Tablet

HOW SUPPLIED

Paliperidone extended-release tablets are available in the following strengths and packages. All tablets are round-shaped.

1.5 mg tablets are brown colored, round shaped, biconvex film coated tablet, imprinted with 'LP1' on one side and plain on other side, and are available in bottles of 30 (NDC 68180-523-06).

3 mg tablets are white colored, round shaped, biconvex film coated tablet, imprinted with 'LP2' on one side and plain on other side, and are available in bottles of 30 (NDC 68180-524-06)

6 mg tablets are beige colored, round shaped, biconvex film coated tablet, imprinted with 'LP3' on one side and plain on other side, and are available in bottles of 30 (NDC 68180-525-06)

9 mg tablets are pink colored, round shaped, biconvex film coated tablet, imprinted with 'LP4' on one side and plain on other side, and are available in bottles of 30 (NDC 68180-526-06)

Odour	Not available
Odour threshold	Not available
Melting point/Freezing Point	Not available
Boiling point	Not available
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	Not available
Vapour 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
Viscosity, kinematic	Not available
Viscosity, dynamic	Not available
Upper flammability limit	Not available
Lower flammability limit	Not available

Section 10: 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	Hazardous Decomposition Products Hydrogen fluoride. Carbon oxides. Nitrogen oxides (NOx), Phosgene.

Section 11: Toxicological Information

Toxicological information

Acute toxicity

Chemical Name	Oral LD50.	Dermal LD50	Inhalation LC50	Intravenous LD50
Paliperidone	65 mg/kg (Rat)	-	-	-

Information on toxicological effects

The toxicological effects of this product have not been thoroughly studied

Section 12: Ecological Information

Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

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

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.