

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Identification

<b>Material</b>	<b>Desvenlafaxine Extended Release Tablets 25 mg, 50 mg and 100 mg</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Goa - 403722 India
<b>Distributor</b>	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

<b>WARNING</b>	Harmful if swallowed
<b>Short Term:</b>	Individuals taking monoamine oxidase (MAO) inhibitors should avoid exposure to this material.
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
<b>Known Clinical Effects:</b>	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, insomnia, nausea, constipation, vomiting, dry mouth, nervousness, anxiety, tremors, impotence, abnormal dreams, abnormal ejaculation, and sweating. Signs and symptoms associated with non-fatal over dosage were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

### Section 3: Composition/Information on Ingredients

#### Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Desvenlafaxine Succinate Monohydrate	386750-22-7

### Section 4: First-Aid Measures

#### First-aid measures

<b>General advice</b>	Consult a physician. Show this safety data sheet to the doctor in attendance.
-----------------------	---

<b>Ingestion</b>	In case of accidental ingestion, remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	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.

## Section 5: Fire-Fighting Measures

<b>Fire-fighting measures</b>	
<b>Fire and Explosion Hazards</b>	Strong dust explosion characteristic. High sensitivity of a dust cloud to ignition, based on minimum ignition energy.
<b>Suitable extinguishing media</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Advise for fire fighters:</b>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Hazardous Combustion Products</b>	Formation of toxic gases is possible during heating or fire.

## Section 6: Accidental Release Measures

<b>Accidental release measures</b>	
<b>Personal Precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Clean-up Methods</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion characteristic and high sensitivity to ignition.

## Section 7: Handling and Storage

<b>Handling and storage</b>	
<b>Precautions for safe handling</b>	<p>Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling.</p> <p>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</p>

**Advice on safe handling**

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

Handle in accordance with good industrial hygiene and safety practice. Conditions for safe storage, including any incompatibilities.

**Storage Conditions**

Store as directed by product packaging.

**Section 8: Exposure Controls/Personal Protection**

**Section 8, Exposure controls/personal protection**

**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. Keep airborne contamination levels below the exposure limits listed above in this section.

**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**

**Physical and chemical properties**

**Physical Form**

Desvenlafaxine extended-release tablets are available as follows:

25 mg, tan, biconvex, round shaped film-coated tablets, debossed with "LU" on one side and "S67" on the other side.

NDC 68180-604-06, bottle of 30 tablets in unit-of-use package  
NDC 68180-604-09, bottle of 90 tablets in unit-of-use package  
NDC 68180-604-02, bottle of 500 tablets

50 mg, light pink, biconvex, round shaped film-coated tablets, debossed with "LU" on one side and "S61" on the other side.

NDC 68180-592-06, bottle of 30 tablets in unit-of-use package  
NDC 68180-592-09, bottle of 90 tablets in unit-of-use package  
NDC 68180-592-02, bottle of 500 tablets

100 mg, reddish-orange, biconvex, round shaped film-coated tablets, debossed with "LU" on one side and "S62" on the other side.

NDC 68180-593-06, bottle of 30 tablets in unit-of-use package  
 NDC 68180-593-09, bottle of 90 tablets in unit-of-use package  
 NDC 68180-593-02, bottle of 500 tablets

Each tablet contains 38 mg, 76 mg or 152 mg of desvenlafaxine succinate monohydrate equivalent to 25 mg, 50 mg or 100 mg of desvenlafaxine, respectively.

The unit-of-use package is intended to be dispensed as a unit.

Appearance	Tablet
Odor	Not available
Odor threshold	Not available
Melting point/freezing point	Not available
Boiling point / boiling range	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

<b>Chemical stability</b>	Stable under normal conditions of use. Keep away from heat and other sources of ignition, including electrostatic discharge.
<b>Possibility of Hazardous Reactions</b>	None known
<b>Incompatible materials</b>	As a precautionary measure, keep away from strong oxidizers.
<b>Hazardous Decomposition Products</b>	No data available

## Section 11: Toxicological Information

### Toxicological information

#### Acute toxicity

Chemical Name	Oral LDmin.	Dermal LD50	Inhalation LC50	Intravenous LD50
Desvenlafaxine Succinate	700 mg/kg (Rat)	-	-	-

## Section 12: Ecological Information

### Ecological Information

NA

## 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

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.