LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	**Clomipramine Hydrochloride Capsules USP** **25 mg, 50 mg, and 75 mg**
Manufacturer	**Lupin Limited** Nagpur 441 108 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

Section 2, Hazard(s) identification

Fire and Explosion

Expected to be non-combustible.

Health

Clomipramine hydrochloride capsules are contraindicated in patients with a history of hypersensitivity to clomipramine hydrochloride capsules or other tricyclic antidepressants.

Monoamine Oxidase Inhibitors (MAOIs)
The use of MAOIs intended to treat psychiatric disorders with clomipramine or within 14 days of stopping treatment with clomipramine hydrochloride capsules is contraindicated because of an increased risk of serotonin syndrome. The use of clomipramine within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated

Starting clomipramine in a patient who is being treated with linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome

Myocardial Infarction
Clomipramine is contraindicated during the acute recovery period after a myocardial infarction.

Environment

No information is available about the potential of this product produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS
Clomipramine Hydrochloride	17321-77-6

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Wash out mouth with water if conscious. Do not induce vomiting unless directed to do so by medical personnel. If large quantities of material are swallowed, obtain medical attention.
Inhalation	Remove from source of exposure. Move individual to fresh air. No inhalation exposure expected with this formulation under normal conditions of use. If symptoms develop, get medical attention.
Skin Contact	Remove contaminated clothing immediately. For accidental and non-therapeutic exposures, immediately flush skin with large amounts of water. If irritation (redness, rash, blistering) develops, get medical attention.
Eye Contact	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	Deaths may occur from overdosage with this class of drugs. Multiple drug ingestion (including alcohol) is common in deliberate tricyclic overdose. As the management is complex and changing, it is recommended that the physician contact a poison control center for current information on treatment. Signs and symptoms of toxicity develop rapidly after tricyclic overdose. Therefore, hospital monitoring is required as soon as possible.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

Section 7: Handling and Storage

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Handling	No special control measures required for the normal handling of this product.
Storage	Store at 25ºC (77°F); excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Dispense in well-closed containers with a child resistant closure. Protect from moisture.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form	**Capsules 25 mg** - Size '2' hard gelatin capsules with melon opaque cap imprinted with 'LU' in black ink and ivory opaque body imprinted with 'C35' in black ink containing white to off white granular powder Bottles of 30 (NDC 68180-492-06); Bottles of 60 (NDC 68180-492-07); Bottles of 90 (NDC 68180-492-09) and Bottles of 100 (NDC 68180-492-01)

Capsules 50 mg - Size '1' hard gelatin capsules with blue opaque cap imprinted with 'LU' in black ink and ivory opaque body imprinted with 'C36' in black ink containing white to off white granular powder

Bottles of 30 (NDC 68180-493-06);
Bottles of 60 (NDC 68180-493-07);
Bottles of 90 (NDC 68180-493-09) and
Bottles of 100 (NDC 68180-493-01)

Capsules 75 mg - Size '1' hard gelatin capsules with yellow opaque cap imprinted with 'LU' in black ink and ivory opaque body imprinted with 'C37' in black ink containing white to off white granular powder

Bottles of 30 (NDC 68180-494-06);
Bottles of 60 (NDC 68180-494-07);
Bottles of 90 (NDC 68180-494-09) and
Bottles of 100 (NDC 68180-494-01)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of carcinogenicity was found in two 2-year bioassays in rats at doses up to 100 mg/kg, which is 24 and 4 times the maximum recommended human daily dose (MRHD) on a mg/kg and mg/m^2 basis, respectively, or in a 2-year bioassay in mice at doses up to 80 mg/kg, which is 20 and 1.5 times the MRHD on a mg/kg and mg/m^2 basis, respectively.

In reproduction studies, no effects on fertility were found in rats given up to 24 mg/kg, which is 6 times, and approximately equal to, the MRHD on a mg/kg and mg/m^2 basis, respectively.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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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

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

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 SDS.