Material Safety Data Sheet

Clomipramine Hydrochloride Capsules

SECTION 1. IDENTIFICATION

Product name	Clomipramine Hydrochloride Capsules USP 25 / 50 / 75 Mg
Formula	$C_{19}H_{23}CLN_2.HCl$
Chemical Name	3-Chloro-5-[3-(dimethylamino) propyl]-10, 11-dihydro5H- dibenz[b,f] azepine monohydrochloride,.
CAS No	17321-77-6
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	Each Clomipramine Hydrochloride Capsules, USP intended for oral administration contains Clomipramine Hydrochloride and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure. Therapeutic agent. Use according to manufacturer's directions.

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:

Registered company name	**Mankind Pharma Ltd**
Address	Unit III, Opp. Dental College, Rampur Ghat Teh. - Paonta Sahib HP-173025 India
Telephone	+91 1704 227600
Fax	Not Available
Website	www.mankindpharma.com
Email	Paonta3@mankindpharma.com

Emergency phone number:

Association/ Organisation	**EHS Department, Unit III, Mankind Pharma Ltd.**
Emergency telephone numbers	**+91 1704 227600 (Mon-Sat, 9 AM to 6PM)**

SECTION 2. HAZARD(S) IDENTIFICATION

Dose and Administration
Initial Treatment/Dose Adjustment (Adults):
Treatment with clomipramine hydrochloride should be initiated at a dosage of 25 / 50 mg/ 75 mg daily (as per physician recommendations) and gradually increased, as tolerated, to approximately 100 mg during the first 2 weeks. During initial titration, clomipramine hydrochloride should be given in divided doses with meals to reduce gastrointestinal side effects. Thereafter, the dosage may be increased gradually over the next several weeks, up to a maximum of 250 mg daily. After titration, the total daily dose may be given once daily at bedtime to minimize daytime sedation.

Adverse Effects:
The most commonly observed adverse events associated with the use of clomipramine hydrochloride and not seen at an equivalent incidence among placebo-treated patients were gastrointestinal complaints, including dry mouth, constipation, nausea, dyspepsia, and anorexia; nervous system complaints, including somnolence, tremor, dizziness, nervousness, and myoclonus; genitourinary complaints, including changed libido, ejaculatory failure, impotence, and micturition disorder; and other miscellaneous complaints, including fatigue, sweating, increased appetite, weight gain, and visual changes.

Over Dose Effect:
Deaths may occur from over dosage 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 centre or nearest hospital for current information on treatment. Signs and symptoms of toxicity develop rapidly after tricyclic overdose. Therefore, hospital monitoring is required as soon as possible.

No teratogenic effects were observed in studies performed in rats and mice at doses up to 100 mg/kg, which is 24 times the maximum recommended human daily dose (MRHD) on a mg/kg basis and 4 times (rats) and 2 times (mice) the MRHD on a mg/m2 basis. Slight non-specific embryo/fetotoxic effects were seen in the offspring of treated rats given 50 and 100 mg/kg and of treated mice given 100 mg/kg.

There are no adequate or well-controlled studies in pregnant women. Withdrawal symptoms, including jitteriness, tremor, and seizures, have been reported in neonates whose mothers had taken clomipramine hydrochloride until delivery. Clomipramine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Nursing Mothers: Clomipramine hydrochloride has been found in human milk. Because of the potential for adverse reactions, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures:

Mixtures

CAS No.	%[Weight]	Name
Not Available		Capsule containing
17321-77-6	<30	Clomipramine Hydrochloride
Not Available		excipients, as
9005-25-8		Starch

112945-52-5		Silica amorphous
557-04-0		Magnesium stearate
Not Available	Balance	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

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 materials 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 prescribed information or to the local poison control information centre or nearest hospital. 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	Death 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 shall contact a poison control centre or nearest hospital 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

Fire and Explosion Hazards	This product is presumed to be 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 media required. For larger amounts (Multiple packages/ pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, SCBA (Self Contained Breathing Apparatus) and full protective equipment are recommended for fire fighters.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Avoid excessive contact and contact with eyes. Wear safety goggles or face 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

Storage	Store at 20° to 25°C (68° to 77°F) Dispense in tight, light-resistant containers with a child resistant closure. Protect from moisture. (note to site : please mention the present storage conditions)
Precautions for safe handling	Keep it dry & in a cool, well ventilated place away from heat. Store in original container
Information about fire - and explosion protection	No special measures required

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

CONTROL PARAMETERS
OCCUPATIONAL EXPOSURE LIMITS (OEL) INGREDIENT DATA:

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US NIOSH Recommended Exposure Limits (RELs)	Starch	Corn starch, Rice starch, Sorghum gum, α-Starch, Starch gum, Tapioca starch	10 (total), 5 (resp) mg/m3	Not Available	Not Available	Not Available
US ACGIH Threshold Limit Values (TLV)	Starch	Starch	10 mg/m3	Not Available	Not Available	TLV® Basis: Dermatitis
US OSHA Permissible Exposure Levels (PELs) - Table Z1	Starch	Starch: Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Levels (PELs) - Table Z1	Starch	Starch: Total dust	15 mg/m3	Not Available	Not Available	Not Available

US NIOSH Recommended Exposure Limits (RELs)	Silica amorphous	Diatomaceous earth, Diatomaceous silica, Diatomite, Precipitated amorphous silica, Silica gel, Silicon dioxide (amorphous)	6 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Levels (PELs) - Table Z3	Silica amorphous	Amorphous	80 / (%SiO2) mg/m3 / 20 mppcf	Not Available	Not Available	(Name (including natural diatomaceous earth))
US OSHA Permissible Exposure Levels (PELs) - Table Z1	Silica amorphous	Silica, amorphous, precipitated and gel	Not Available	Not Available	Not Available	
US OSHA Permissible Exposure Levels (PELs) - Table Z1	Silica amorphous	Silica, amorphous, diatomaceous earth, containing less than 1% crystalline silica	Not Available	Not Available	Not Available	
US OSHA Permissible Exposure Levels (PELs) - Table Z1	Silica amorphous	Silica, fused, respirable dust	Not Available	Not Available	Not Available	
US ACGIH Threshold Limit Values (TLV)	Magnesium stearate	* Stearates(J)	10; 3 mg/m3	Not Available	Not Available	TLV® Basis: LRT irr

EMERGENCY LIMITS:

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Starch	Thyodene; (Amylodextrin)	30 mg/m3	330 mg/m3	2,000 mg/m3
Silica amorphous	Silica gel, amorphous synthetic	18 mg/m3	200 mg/m3	1,200 mg/m3
Silica amorphous	Silica, amorphous fumed	18 mg/m3	100 mg/m3	630 mg/m3
Silica amorphous	Siloxanes and silicones, dimethyl, reaction products with silica; (Hydrophobic silicon dioxide, amorphous)	120 mg/m3	1,300 mg/m3	7,900 mg/m3
Silica amorphous	Silica, amorphous fume	45 mg/m3	500 mg/m3	3,000 mg/m3
Silica amorphous	Silica, amorphous hydrated	18 mg/m3	220 mg/m3	1300 mg/m3

Ingredient	Original IDLH	Revised IDLH
Clomipramine hydrochloride	Not Available	Not Available
Starch	Not Available	Not Available
Silica amorphous	3,000 mg/m3	Not Available
Magnesium stearate	Not Available	Not Available

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Appearance	Capsules.		
Physical state	Divided Solid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Applicable
pH (as supplied)	Not Available	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Applicable
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	Not Applicable	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Not Applicable	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Applicable	**Surface Tension (dyn/cm or mN/m)**	Not Applicable
Lower Explosive Limit (%)	Not Applicable	**Volatile Component (%vol)**	Negligible
Vapour pressure (kPa)	Not Applicable	**Gas group**	Not Available
Solubility in water	Not Available	**pH as a solution (1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available
Conditions to avoid	Contact with incompatible materials		

SECTION 10. STABILITY AND REACTIVITY

The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability	Material is stable under normal conditions.
Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Decomposition Products	When heated to decomposition, emits dangerous fumes.
Incompatible Materials	Strong oxidizing agent

SECTION 11. TOXICOLOGICAL INFORMATION

General
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Ingestion
Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Other
Not Available

Symptoms related to the physical, chemical and Toxicological characteristics
Not Available

Information on toxicological effects
Acute toxicity
Not available

Further information
Not available

SECTION 12. ECOLOGICAL INFORMATION

No relevant studies identified.

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

Generic Medicine. Approved by USFDA.

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.

Mankind shall not be held liable for any damage resulting from handling or from contact with product. Mankind reserves the right to revise the SDS.

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