



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Material	Citalopram Hydrobromide Oral Solution, 10 mg/5 mL
Other means of identification	None.
Recommended use	Treatment of depression
Recommended restrictions	None known.
Manufacturer	Hetero Labs Limited Unit III 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854

Section 2: Hazard(s) Identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	Warning
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials. Store at 20° to 25°C (68° to 77°F). Keep Citalopram oral solution bottle closed tightly.
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.
Hazard(s) not otherwise classified (HNOC)	None known.

Section 3: Composition/Information on Ingredients

%	10mg/5mL
CAS	59729-32-7

Section 4: First-Aid Measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.



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Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Possible common side effects are: nausea, sleepiness, weakness, dizziness, feeling anxious, trouble sleeping, sexual problems, sweating, shaking, dry mouth
Indication of immediate medical attention and special treatment needed	In the case of overdose, the primary management should be the reestablishment of adequate ventilation with mechanical assistance of respiration, if required. Gastric evacuation by lavage and use of activated charcoal should be considered. Careful observation and cardiac and vital sign monitoring are recommended, along with general symptomatic and supportive care.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Section 5: Fire-Fighting Measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Firefighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
Environmental Precautions	Avoid discharge into drains, water courses or onto the ground

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store away from incompatible materials (see Section 10 of the SDS). Store away from incompatible materials. Store at 20° to 25°C (68° to 77°F). Keep Citalopram oral solution bottle closed tightly. Keep out of the reach of children.

Section 8: Exposure Controls/Personal Protection

Occupational exposure	No exposure limits noted for ingredient(s).
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limits

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Ventilation should be matched to conditions.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection For consumer use, no unusual precautions are necessary.

Other None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Appearance Clear, colorless solution.

Physical state Liquid.

Form Liquid.

Color Clear colorless.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.



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Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit – lower (%)	Not available.
Flammability limit – upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Sparingly soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Exposure to light.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

Section 11: Toxicological Information

Information on likely routes of exposure	
Inhalation	Not expected to be hazardous in final pharmaceutical form.
Skin contact	Not expected to be hazardous in final pharmaceutical form.
Eye contact	Not expected to be hazardous in final pharmaceutical form.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	Possible common side effects are: nausea, sleepiness, weakness, dizziness, feeling anxious, trouble sleeping, sexual problems, sweating, shaking, dry mouth
Information on toxicological effects	
Acute toxicity	Not expected to be acutely toxic.
Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Under normal conditions of intended use, this material does not pose a eye hazard.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.



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Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	This product is not expected to be mutagenic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA,
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
Reproductive toxicity	Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Product is excreted in human milk. Human milk feeding by a mother is not expected to harm an infant, provided maternal serum calcium levels are appropriately monitored
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Aspiration hazard	See package insert.

Section 12: Ecological Information

Ecotoxicity	The product is not classified as environmentally hazardous.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	None.

Section 13: Disposal Considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport Information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

Section 15: Regulatory Information



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US federal regulations This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations Drug Enforcement Administration (DEA): Citalopram hydrobromide is not a controlled substance.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Not listed.

US state regulations

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.

US. Rhode Island RTK
Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial	Yes



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Europe	Chemical Substances (EINECS) European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16: Other Information, including date of preparation or last revision

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS