



# 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	
<b>Section 1, Identification</b>	
<b>Material</b>	<b>Escitalopram Oxalate Oral Solution, 5 mg /5 mL</b>
<b>Manufacturer</b>	<b>Hetero Labs Limited Unit III</b> 22-110, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.,</b> Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Section 2, Hazard(s) identification</b>	
<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. Caution - Pharmaceutical agent. Possible effects of overexposure in the workplace include: headache; nausea.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
<b>Section 3, Composition/information on ingredients</b>	
<b>Ingredients</b>	Escitalopram Oxalate
<b>CAS</b>	219861-08-2
Section 4: First-Aid Measures	
<b>Section 4, First-aid measures</b>	
<b>Ingestion</b>	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.
Section 5: Fire-Fighting Measures	
<b>Section 5, Fire-fighting measures</b>	
<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Fire fighting Procedures</b>	For single units (packages): No special requirements needed. 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, self contained breathing apparatus and full protective equipment are recommended for fire-fighters
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.



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## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## Section 7: Handling and Storage

### Section 7, Handling and storage

<b>HANDLING</b>	No special control measures required for the normal handling of this product.
<b>STORAGE</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

## 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

<b>Physical Form</b>	<b>Escitalopram Oxalate Oral Solution, 5 mg /5 mL</b> 5mg/5ml, Peppermint flavour (240ml), Bottles of 240 ml with Induction Sealing FSE Wad (NDC 31722-569-24)
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## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Carcinogenesis, Mutagenesis, Impairment of Fertility

#### Carcinogenesis

Racemic citalopram was administered in the diet to NMR1/BOM strain mice and COBS WI strain rats for 18 and 24 months, respectively. There was no evidence for carcinogenicity of racemic citalopram in mice receiving up to 240 mg/kg/day. There was an increased incidence of small intestine carcinoma in rats receiving 8 or 24 mg/kg/day racemic citalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown.

#### Mutagenesis

Racemic citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 and TA1537) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Racemic citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in a coupled *in vitro/in vivo* unscheduled DNA synthesis (UDS)



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assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays.

#### **Impairment of Fertility**

When racemic citalopram was administered orally to 16 male and 24 female rats prior to and throughout mating and gestation at doses of 32, 48, and 72 mg/kg/day, mating was decreased at all doses and fertility was decreased at doses  $\geq$  32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day.

### Section 12: Ecological Information

#### **Section 12: Ecological Information**

No relevant studies identified.

### Section 13: Disposal Considerations

#### **Section 13: Disposal Considerations**

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

### Section 14: Transport Information

#### **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

#### **Section 15: Regulatory Information**

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.

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.