

# **MATERIAL SAFETY DATA SHEET**

## **1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY**

<b>Material</b>	<b>Escitalopram Tablets USP</b> <b>5 mg, 10 mg and 20 mg</b>
<b>Manufacturer</b>	Lupin Limited Goa 403 722 INDIA
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 <sup>st</sup> Floor 111, South Calvert Street Baltimore, MD 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

## **2. COMPOSITION / INFORMATION ON INGREDIENTS**

<b>Ingredients</b>	<b>CAS</b>
<b>Escitalopram Oxalate</b>	219861-08-2

## **3. HAZARD IDENTIFICATION**

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Escitalopram is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Escitalopram Tablets.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

## **4. FIRST AID MEASURE**

<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.
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<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.

## NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	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.
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<b>OVERDOSAGE</b>	In clinical trials of escitalopram, there were reports of escitalopram overdose, including overdoses of up to 600 mg, with no associated fatalities. During the postmarketing evaluation of escitalopram, escitalopram overdoses involving overdoses of over 1000 mg have been reported. As with other SSRIs, a fatal outcome in a patient who has taken an overdose of escitalopram has been rarely reported.
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Symptoms most often accompanying escitalopram overdose, alone or in combination with other drugs and/or alcohol, included convulsions, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence, and ECG changes (including QT prolongation and very rare cases of torsade de pointes). Acute renal failure has been very rarely reported accompanying overdose.

## 5. FIRE FIGHTING MEASURE

<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 Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## 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.

## 7. HANDLING AND STORAGE

<b>Handling</b>	No special control measures required for the normal handling of this product.
<b>Storage</b>	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical Form</b>	Each film coated round tablet contains escitalopram oxalate equivalent to the labeled amount of escitalopram as follows.
	5 mg Tablets: White to off-white, round, film coated tablets, debossed with "LU" on one side and "W21" on the other side
	Bottles of 30 NDC 68180-137-06
	Bottles of 100 NDC 68180-137-01
	10 mg Tablets: White to off-white, round, film coated tablets, debossed with 'L' and 'U' either side of the scoreline on one side and 'W22' on the other side.
	Bottles of 100 NDC 68180-135-01
	20 mg Tablets: White to off-white, round, film coated tablets, debossed with 'L' and 'U' either side of the scoreline on one side and 'W23' on the other side.
	Bottles of 100 NDC 68180-136-01

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## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

### Carcinogenesis, Mutagenesis, Impairment of Fertility

#### ***Carcinogenesis***

Racemic citalopram was administered in the diet to NMRI/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) 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.

## 12. ECOLOGICAL INFORMATION

No relevant studies identified.

## 13. DISPOSAL CONSIDERATION

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

## 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

## 15. REGULATORY INFORMATION

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

## 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 MSDS.