



SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: Lexapro® (Escitalopram Oxalate) Oral Solution

DESCRIPTION: Escitalopram Oxalate Aqueous Solution

CHEMICAL NAME: For Active Ingredient: S-(+)-1-[3(dimethyl-amino)propyl]-1-(p-fluorophenyl)-5-phthalanarbonitrile oxalate

CHEMICAL FAMILY: For Active Ingredient: Furancarbonitrile

FORMULA: For Active Ingredient: C₂₀H₂₁FN₂O • C₂H₂O₄

RELEVANT USE of the SUBSTANCE: Human Pharmaceutical

USES ADVISED AGAINST: Non-Pharmaceutical Use

HOW SUPPLIED: 5 mg/5 mL (240 mL) Oral Escitalopram Oxalate Solution

OTHER DESIGNATIONS: NDC: 0456-2101-08

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:

U.S. ADDRESS:

Allergan

5 Giralda Farms

Madison, NJ 07940

U.S. BUSINESS PHONE/GENERAL SDS INFORMATION:

1-800-272-5525

RESPONSIBLE PARTY EUROPE:

EUROPEAN ADDRESS:

EUROPEAN BUSINESS PHONE:

EMERGENCY PHONE (U.S./NORTH AMERICA): CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico

EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

Email:

SDS@Allergan.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: December 12, 2017

DATE OF REVISION: New

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW:

Product Description: This product is white liquid with a peppermint odor.

Health Hazards: Accidental ingestion may be harmful. Inhalation and eye contact may cause irritation. In therapeutic use, the most common side effect reported have included nausea, sleepiness, weakness, dizziness, feeling anxious, difficulty sleeping, sexual dysfunction, sweating, tremors, lack of hunger, dry mouth, constipation, infection and yawning. Therapeutic use can cause adverse effects on the central nervous, blood and gastrointestinal systems. Potential harm to fetus, based on animal data. More information on adverse effects from therapeutic use is described in Section 11 (Toxicological Information).

Flammability Hazards: This product is not flammable. If involved in a fire, the water component may evaporate and the residual may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sodium and nitrogen oxides, hydrogen fluoride and acrolein).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Other Hazards: No other hazard information currently known.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENT:				
Escitalopram Oxalate S-(+)-1-[3(dimethyl- amino)propyl]-1-(p- fluorophenyl)-5- phthalanarbonitrile oxalate	219861-08-2	Not Listed	Proprietary	SELF-CLASSIFICATION: <u>EU 67/548</u> Classification: Reproductive Toxicity Cat. 3 Risk Phrase Codes: R63 Hazard Symbol: Xn <u>GHS & EU 1272/2008</u> Classification: Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 5 Hazard Codes: H361, H303 Hazard Symbol/Pictogram: GHS08
EXCIPIENTS:				
Citric Acid	77-92-9	201-069-1	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Irritant Risk Phrases: R38, R41 Hazard Symbol: Xi <u>EU/GHS 1272/2008</u> Classification: Acute Oral Toxicity Cat. 5, Skin Irritation Cat. 2, Eye Damage Cat. 1 Hazard Statement Codes: H303, H315, H318 Hazard Symbol/Pictogram: GHS05, GHS07, GHS08
Glycerin	56-81-5	200-289-5	Proprietary	SELF-CLASSIFICATION: <u>EU (67/548/EEC):</u> Classification: Not Applicable <u>EU/GHS 1272/2008:</u> Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: None Applicable
Malic Acid	6915-15-7	230-022-8	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Harmful, Irritant Risk Phrases: R22, R37/38, R41 Hazard Symbol: Xi <u>EU/GHS 1272/2008</u> Classification: Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Damage Cat. 1, STOT (Inhalation-Respiratory Irritation) Se Cat. 3 Hazard Statement Codes: H302, H315, H318 Hazard Symbol/Pictogram: GHS05, GHS07, GHS08
Methyl Paraben	99-76-3	202-785-7	Proprietary	SELF CLASSIFICATION <u>EU (67/548/EEC):</u> Classification: Not Applicable Risk Phrases: Not Applicable Symbols: Applicable <u>EU/GHS 1272/2008:</u> Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: Not Applicable
Natural Peppermint Flavoring	Mixture	Mixture	Proprietary	<u>EU 67/548 Hazard Classification:</u> Not Applicable <u>EU/GHS 1272/2008 Classification:</u> Not Applicable
Propyl Paraben	94-13-3	202-307-7	Proprietary	<u>EU 67/548 Hazard Classification:</u> Not Applicable <u>GHS and EU 1272/2008 Hazard Classification:</u> Not Applicable
Sodium Citrate	68-04-2	200-675-3	Proprietary	<u>EU 67/548 Hazard Classification:</u> Not Applicable <u>GHS and EU 1272/2008 Hazard Classification:</u> Not Applicable
Sorbitol	50-70-4	200-061-5	Proprietary	<u>EU 67/548 Hazard Classification:</u> Not Applicable <u>EU/GHS 1272/2008 Classification:</u> Not Applicable
Water	7732-18-5	231-791-2	Balance	<u>EU 67/548 Hazard Classification:</u> Not Applicable <u>EU/GHS 1272/2008 Classification:</u> Not Applicable

See Section 1 for full classification information.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Upon contact of this material with skin, eyes, or mucous membranes, immediately decontaminate by flushing with water for at least 20 minutes. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

Inhalation: If mists or sprays from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

Skin Exposure: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

Eye Exposure: If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

4 FIRST-AID MEASURES (Continued)

DESCRIPTION OF FIRST AID MEASURES (continued):

Ingestion Exposure: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing renal or hepatic disorders may be aggravated by exposure to this product. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to this material or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. There is no specific antidote for this drug. Treatment should be supportive and symptomatic. Establish and maintain an airway to ensure adequate ventilation and oxygenation. 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. Due to the large volume of distribution of Escitalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit.

5. FIRE-FIGHTING MEASURES

FLASHPOINT: Not flammable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

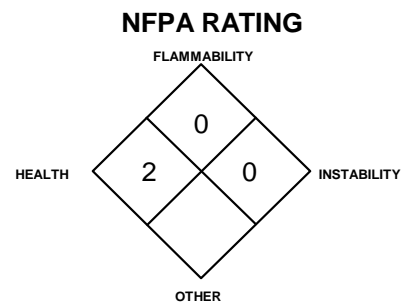
UNSUITABLE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE PRODUCT: This product is not flammable. If involved in a fire, the water component may evaporate and the residual may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sodium and nitrogen oxides, hydrogen fluoride and acrolein).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.



Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 =

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.**

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Absorb up spilled material with damp sponge, polypads or other suitable material.

Large Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of mists or sprays onto polypads or other non-reactive absorption.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing immediately. Keep container tightly closed when not in use. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Store at 20-25°C (68-77°F) and away from moisture, humidity and light. Product should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Occupational/Workplace Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							OTHER mg/m ³
		ACGIH-TLV		OSHA-PEL		NIOSH-REls		NIOSH IDLH mg/m ³	
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³		
Escitalopram Oxalate	59277-89-3	NE	NE	NE	NE	NE	NE	NE	Allergan OEL: 4 µg/m ³
Citric Acid	77-92-9	NE	NE	NE	NE	NE	NE	NE	NE
Glycerin	56-81-5	NE	NE	15 (total dust) 5 (resp. fract.) 10 (total) 5 (resp. fract.) [vacated 1989 PEL]	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable fraction) PEAK = 2•MAK 15 min, average value, 1-hr interval, 4 per shift Pregnancy Risk Classification: C
Malic Acid	6915-15-7	NE	NE	NE	NE	NE	NE	NE	NE
Methyl Paraben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Natural Peppermint Flavoring Mixture		NE	NE	NE	NE	NE	NE	NE	NE
Propyl Paraben	94-13-3	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Citrate	68-04-2	NE	NE	NE	NE	NE	NE	NE	NE
Sorbitol	50-70-0	NE	NE	NE	NE	NE	NE	NE	NE
Water, Purified	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Other Terms Used.

International Occupational Exposure Limits: Currently, the following exposure limits have been established by various countries for components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

CITRIC ACID:

Russia: STEL = 1 mg/m³, JUN 2003

GLYCERIN:

Belgium: TWA = 10 mg/m³, MAR 2002

Finland: TWA = 20 mg/m³, NOV 2011

France: VME = 10 mg/m³, FEB 2006

Germany: MAK = 50 mg/m³, inhal, 2011

Korea: TWA = 10 mg/m³ (mist), 2006

Mexico: TWA = 10 mg/m³ (inhalable), 2004

The Netherlands: MAC-TGG = 10 mg/m³, 2003

New Zealand: TWA = 10 mg/m³ (mist), JAN 2002

GLYCERIN (continued):

Peru: TWA = 10 mg/m³, JUL 2005

Switzerland: MAK-W = 50 mg/m³, KZG-W = 100 mg/m³, inhal, JAN 2011

United Kingdom: TWA = 10 mg/m³, OCT2007

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

METHYL PARABEN:

Russia: STEL = 4 mg/m³, JUN 2003

PROPYL PARABEN:

Russia: STEL = 10 mg/m³, JUN 2003

SORBITOL:

Russia: STEL = 10 mg/m³, JUN 2003

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

Respiratory Protection: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PERSONAL PROTECTIVE EQUIPMENT (continued):

Eye Protection: During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

Body Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: Liquid.

ODOR: Peppermint.

COLOR: As described in Section 2.

ODOR THRESHOLD: Not available.

HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following information is for the Escitalopram Oxalate active ingredient.

FORM: Crystalline powder.

MOLECULAR WEIGHT: 414.42

ODOR: Odorless.

DENSITY: Not available.

MELTING/FREEZING POINT: Decomposes.

FLASH POINT: 212.8°C (415.04°F) [predict.]

VAPOR PRESSURE @ 25°C: 1.53E-07 mmHg [predict.]

OTHER SOLUBILITIES: Freely soluble in methanol and dimethyl sulfoxide (DMSO), soluble in isotonic saline solution, sparingly soluble in ethanol, slightly soluble in ethyl acetate, and insoluble in heptane.

COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Log P = 2.514 [predict.]

COLOR: White to slightly yellow.

MOLECULAR FORMULA: C₂₀H₂₁FN₂O • C₂H₂O₄

ODOR THRESHOLD: Not applicable.

pH: Not applicable.

BOILING POINT @ 760 mmHg: 428.3°C (802.94°F) [predict.]

AUTOIGNITION TEMPERATURE: Not available.

SOLUBILITY IN WATER: Sparingly soluble.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable under normal conditions of storage.

HAZARDOUS DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, sodium and nitrogen oxides, hydrogen fluoride and acrolein). **Hydrolysis:** None known.

INCOMPATIBLE MATERIALS: This compound is incompatible with strong oxidizers, strong acids.

POSSIBILITY OF HAZARDOUS REACTIONS/ POLYMERIZATION: No data available.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to employee handling in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation of airborne aerosols generated by this product may irritate the nose, throat, and lungs. No other effects by inhalation are known.

Skin Contact: Contact with the skin may cause irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).

Eye Contact: Contact with the eyes of aerosols generated by this product may cause irritation, redness, and tearing.

Skin Absorption: No information available.

Ingestion: Ingestion is not a significant route of occupational exposure. Symptoms of acute ingestion may include those described under 'Other Health Effects'.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may also include those described under 'Other Health Effects'.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effects reported have included malaise, headache, diarrhea, nausea and/or vomiting. Therapeutic use can cause adverse effects on the central nervous and gastrointestinal systems. Allergic reactions, sometimes serious, have been reported. Limited evidence of carcinogenic and mutagenic effect, based on animal data. Other adverse effects reported from therapeutic use described by body system are provided below.

- **Blood and Lymphatic System:** Anemias including aplastic anemia and hemolytic anemia, abnormal production of white blood cells, decrease in the number of white blood cells, blood platelet decrease, sometimes with bruising.
- **Body as a Whole:** Fatigue, dry mouth, increased sweating, influenza-like symptoms, decreased appetite.
- **Central Nervous System:** Dizziness, insomnia, somnolence, sensations of tickling, tingling, burning, pricking, or numbness, headache.



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
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FLAMMABILITY HAZARD	(RED)	0
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PHYSICAL HAZARD	(YELLOW)	0
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PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued):

- **Gastrointestinal System:** Diarrhea, constipation, indigestion, nausea, abdominal pain, vomiting, abdominal pain, flatulence.
- **Musculoskeletal System:** Muscle pain.
- **Psychiatric Symptoms:** Abnormal dreams, lethargy.
- **Reproductive System:** Potential harm to fetus, decreased libido, ejaculation disorder, failure to ejaculate, impotence, menstrual disorders.
- **Respiratory System:** Runny nose, sinus irritation.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: This product may cause irritation via inhalation or inhalation, skin or eye contact.

Chronic: Potential fetal harm. Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause adverse symptoms as described under 'Other Health Effects'.

TARGET ORGANS: Acute: Workplace Exposure: Skin and organs described under 'Other Potential Health Effects'. Therapeutic Doses: Skin. **Chronic:** Workplace Exposure: Skin. Therapeutic Doses: Skin and organs described under 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION TO THE PRODUCT: In therapeutic use, facial swelling and skin reactions, including hair loss, erythema multiforme (tissue itching, swelling, lesions, joint aches), photosensitive rash, Stevens-Johnson Syndrome (painful red or purplish rash that spreads and blisters, followed by the top layer of the affected skin death and shedding of skin), toxic epidermal necrolysis (skin reaction that can cause destruction of skin and can be fatal), and hives have been reported. Some sensitization effects from skin contact of parabens have been reported.

TOXICITY DATA: Currently the following toxicity data are available for the active ingredient. Additional data are available, for excipients, but are not presented in this SDS. Contact Allergan for more information.

ESCITALOPRAM OXALATE:

TDLo (Oral-Rat) 6.8 mg/kg: Behavioral: alteration of classical conditioning
TDLo (Subcutaneous-Rat) 0.24 mg/kg: Behavioral: anti-anxiety
TDLo (Subcutaneous-Rat) 0.81 mg/kg: Behavioral: alteration of classical conditioning
TDLo (Subcutaneous-Rat) 0.15 mg/kg: Brain and Coverings: other degenerative changes: Biochemical: Metabolism (Intermediary): other
TDLo (Subcutaneous-Mouse) 0.36 mg/kg: Behavioral: alteration of classical conditioning
TDLo (Subcutaneous-Mouse) 4 mg/kg: Behavioral: antipsychotic
TDLo (Subcutaneous-Mouse) 5 mg/kg: Behavioral: changes in psychophysiological tests

ESCITALOPRAM OXALATE (continued):

TDLo (Subcutaneous-Mouse) 140 mg/kg/28 days-intermittent: Behavioral: changes in psychophysiological tests
TDLo (Intravenous-Rat) 0.05 mg/kg: Brain and Coverings: recordings from specific areas of CNS
TDLo (Subcutaneous-Mouse) 0.01 mg/kg: Behavioral: anti-anxiety, changes in psychophysiological tests
TDLo (Subcutaneous-Mouse) 0.3 mg/kg: Behavioral: changes in motor activity (specific assay)

CARCINOGENIC POTENTIAL: The following information is available for the active ingredient.

Racemic Escitalopram 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 Escitalopram 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 Escitalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown. This compound has not been listed by any agencies tracking the carcinogenic potential of chemical compounds.

The remaining components are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Escitalopram Oxalate in pregnant women. This product is rated Pregnancy Risk Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.)

Mutagenicity: Racemic Escitalopram 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 Escitalopram 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.

Embryotoxicity/Teratogenicity: In a rat embryo/fetal development study, oral administration of Escitalopram (56, 112, or 150 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased fetal body weight and associated delays in ossification at the two higher doses (approximately ≥ 56 times the maximum recommended human dose [MRHD] of 20 mg/day on a body surface area [mg/m^2] basis). Maternal toxicity (clinical signs and decreased body weight gain and food consumption), mild at 56 mg/kg/day, was present at all dose levels. The developmental no-effect dose of 56 mg/kg/day is approximately 28 times the MRHD on a mg/m^2 basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a mg/m^2 basis). When female rats were treated with Escitalopram (6, 12, 24, or 48 mg/kg/day) during pregnancy and through weaning, slightly increased offspring mortality and growth retardation were noted at 48 mg/kg/day which is approximately 24 times the MRHD on a mg/m^2 basis. Slight maternal toxicity (clinical signs and decreased body weight gain and food consumption) was seen at this dose. Slightly increased offspring mortality was also seen at 24 mg/kg/day. The no-effect dose was 12 mg/kg/day which is approximately 6 times the MRHD on a mg/m^2 basis. In animal reproduction studies, racemic citalopram has been shown to have adverse effects on embryo/fetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic doses. In two rat embryo/fetal development studies, oral administration of racemic citalopram (32, 56, or 112 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased embryo/fetal growth and survival and an increased incidence of fetal abnormalities (including cardiovascular and skeletal defects) at the high dose.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Embryotoxicity/Teratogenicity (continued): This dose was also associated with maternal toxicity (clinical signs, decreased body weight gain). The developmental no-effect dose was 56 mg/kg/day. In a rabbit study, no adverse effects on embryo/fetal development were observed at doses of racemic citalopram of up to 16 mg/kg/day. Thus, teratogenic effects of racemic citalopram were observed at a maternally toxic dose in the rat and were not observed in the rabbit. When female rats were treated with racemic citalopram (4.8, 12.8, or 32 mg/kg/day) from late gestation through weaning, increased offspring mortality during the first 4 days after birth and persistent offspring growth retardation were observed at the highest dose. The no-effect dose was 12.8 mg/kg/day. Similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses \geq 24 mg/kg/day. A no-effect dose was not determined in that study.

Reproductive Toxicity: Acyclovir did not impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). In the mouse study, plasma levels were 9 to 18 times human levels, while in the rat study, they were 8 to 15 times human levels. At higher doses (50 mg/kg/day, s.c.) in rats and rabbits (11 to 22 and 16 to 31 times human levels, respectively) implantation efficacy, but not litter size, was decreased. In a rat peri- and post-natal study at 50 mg/kg/day, s.c., there was a statistically significant decrease in group mean numbers of corpora lutea, total implantation sites, and live fetuses. No testicular abnormalities were seen in dogs given 50 mg/kg/day, IV for 1 month (21 to 41 times human levels) or in dogs given 60 mg/kg/day orally for 1 year (6 to 12 times human levels). Testicular atrophy and aspermatogenesis were observed in rats and dogs at higher dose levels. Acyclovir concentrations have been documented in breast milk in 2 women following oral administration of acyclovir and ranged from 0.6 to 4.1 times corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg/day. Because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

Non-Teratogenic Effects: Neonates exposed to Lexapro[®] and other SSRIs or serotonin and norepinephrine reuptake inhibitors (SNRIs), late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome. Infants exposed to SSRIs in pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1 - 2 per 1,000 live births in the general population and is associated with substantial neonatal morbidity and mortality. Several recent epidemiologic studies suggest a positive statistical association between SSRI use (including Lexapro[®]) in pregnancy and PPHN. Other studies do not show a significant statistical association.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY IN SOIL: This product has not been tested for mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIO-ACCUMULATIVE POTENTIAL: No information available.

ECOTOXICITY: No data is available for this product. All releases to terrestrial, atmospheric and aquatic environments should be avoided.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: This material has no known ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

14. TRANSPORTATION INFORMATION (Continued)

INTERNATIONAL MARITIME ORGANIZATION (IMO): This product is NOT classified as Dangerous Goods, per rules of IMO.

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) nor a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component of this product is on the California Proposition 65 Lists.

CANADIAN REGULATIONS:

Canadian DSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is excepted from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Canadian WHMIS Classification and Symbol: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal product for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

U.S. ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING!** MAY BE HARMFUL IF ACCIDENTALLY INGESTED. MAY CAUSE ADVERSE EFFECTS SYSTEMIC EFFECTS IF LARGE AMOUNTS ARE SWALLOWED. BASED ON ANIMAL DATA, INGESTION MAY BE HARMFUL TO FETUS. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting. Seek immediate medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or "alcohol" foam. **IN CASE OF SPILL:** Absorb spilled product with appropriate materials/absorbent. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Escitalopram Oxalate: This is a self-classification.

Classification: Reproductive Toxicity Category 2, Acute Oral Toxicity Category 4

Hazard Statements: H361d: Suspected of damaging the unborn child. H302: Harmful if swallowed.

Citric Acid, Anhydrous: This is a self-classification.

Classification: Acute Oral Toxicity Category 5, Skin Irritation Category 2, Eye Damage Category 1B

Hazard Statements: H303: May be harmful if ingested. H315: Causes skin irritation. H318: Causes serious eye damage.

Glycerin, Methyl Paraben: This is a self-classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if ingested.

16. OTHER INFORMATION (Continued)

CLASSIFICATION OF COMPONENTS (continued):

CLP Regulation (EC) 1272/2008 (continued):

Malic Acid:

Classification: Acute Oral Toxicity Category 4, Skin Irritation Category 2, Eye Damage Category 1B, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3

Hazard Statements: H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation.

All Other Components: An official classification for these substances has not been published nor is applicable.

67/548/EEC:

Escitalopram Oxalate: This is a self-classification.

Classification: Reproductive Toxicity Category 3, Harmful

Risk Phrases: R63: Possible risk of harm to the unborn child. R22: Harmful if swallowed.

Citric Acid:

Classification: Irritant

Risk Phrases: R38: Irritating to skin. R41: Risk of serious damage to eyes.

Malic Acid:

Classification: Harmful, Irritant

Risk Phrases: R22: Harmful if swallowed. R37/38: Irritating to respiratory system and skin. R41: Risk of serious damage to eyes.

All Other Components: An official classification for these substances has not been published nor is applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: New

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

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This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Allergan knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.