APOTEX
ADVANCING GENERICS

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Duloxetine Delayed-Release Capsules USP**

Recommended use : Pharmaceutical industry: Dosage form
Therapeutic category: Antidepressant.

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

Supplier :

Canada

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+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Duloxetine hydrochloride	136434-39-9	30 - 60

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not available

Synonyms : Not available.

Chemical family : Naphthyl ether amine

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

Eye contact : Flush with copious quantities of water. If irritation persists, obtain medical advice.

Skin contact : Flush with copious amounts of water. Seek medical attention if irritation persist.

Inhalation : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Potential acute and delayed health effects : Refer to Sec. 11

Section 5. Fire Fighting Measures

Specific hazard arising from the chemical : During fire, gases hazardous to health may be formed.

Suitable extinguishing media and special protective equipment for firefighters : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Methods and materials for containment and cleaning up : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.

Protective equipment and personal precautions : Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, refer to section 8 of the SDS.

Section 7. Handling and Storage

Precautions for safe handling : Avoid breathing dust.

Conditions for safe storage : Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Section 8. Exposure Controls/Personal Protection

Engineering Controls : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, appropriate PPE may be required that includes NIOSH approved respirators.

EYE/FACE PROTECTION: Wear approved safety eyewear if eye contact is possible.

SKIN PROTECTION: Where there is a risk of contact when handling, wear suitable skin protection (e.g., gloves, lab coat/uniform) having resistance to the product.

HYGIENE MEASURES: In the event clothing becomes contaminated, remove promptly. Launder before use. When handlings, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : Capsules.

pH : Not available.

Melting point/ Freezing point : Not available.

Boiling point : Not available.

Volatility : Not available.

Specific gravity : Not available.

Evaporation rate : Not available.

Vapor density : Not available.

Relative density : Not available.

Vapor pressure : Not available.

Odor : Not available.

Odor threshold : Not available.

Conditions of instability : No additional remark.

Decompositon temperature : Not available.

Partition Coefficient: : Not available.

Viscosity : Not available.

Flash points : Not available.

Flammable limits : Not available.

Autoignition temperature : Not available.

Flammability : Emits toxic fumes under fire conditions.

Solubility : Not available.

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable.

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : When heated to decomposition material emits toxic fumes.

Incompatible materials/ Conditions to avoid : Not available.

Section 11. Toxicological Information

Information on the likely routes of exposure : As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances.

Toxicity data : LD50: 491 mg/kg (oral-male rat)
LD50: 279 mg/kg (oral-female rat)
Skin, rabbit, 1000 mg/kg - no deaths or toxicity
Irritancy test:
Rabbit-eye: corrosive
Rabbit-skin: slight irritant

Delayed and immediate effects and also chronic effects from short and long term exposure : Possible hypersensitization.
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. In female mice receiving duloxetine at 140 mg/kg/day (11 times the maximum recommended human dose [MRHD, 60 mg/day] and 6 times the human dose of 120 mg/day on a mg/m 2 basis), there was an increased incidence of hepatocellular adenomas and carcinomas. The no-effect dose was 50 mg/kg/day (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m 2 basis). Reproductive Toxicity: Duloxetine administered orally to either male or female rats prior to and throughout mating at doses up to 45 mg/kg/day (7 times the maximum recommended human dose of 60 mg/day and 4 times the human dose of 120 mg/day on a mg/m 2 basis) did not alter mating or fertility.

Teratogenicity: Pregnancy Category: C. In animal reproduction studies, duloxetine has been shown to have adverse effects on embryo/fetal and postnatal development.

Mutagenicity: Duloxetine was not mutagenic in the in vitro bacterial reverse mutation assay (Ames test) and was not clastogenic in an in vivo chromosomal aberration test in mouse bone marrow cells.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material.

Symptoms related to the physical, chemical and toxicological characteristics : Most common adverse reactions (≥5% and at least twice the incidence of placebo patients): nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label	Additional information (e.g., special precautions, environmental hazards, transport in bulk)
TDG- road Canada/U.S.			Not regulated.			
ICAO-Air			Not regulated.			
ADR			Not regulated.			
IMDG Class			Not regulated.			

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS

Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RxList Monographs
U.S. Pharmacopeia
Apotex Product Monograph

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Notice to Reader

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