

Material Safety Data Sheet

| Section 1. Product Identification and Uses | | | |
|---|--|---------------------------|---|
| Common/Trade name | Trazodone Hydrochloride Tablets USP, 50 mg, 100 mg, 150 mg and 300 mg | DSL# | Not on the DSL list. |
| Synonyms | Brand Name: Desyrel | CAS# | Not applicable. |
| Chemical name | Not applicable. | Molecular weight | Not applicable. |
| Chemical family | Not applicable. | Chemical formula | Not applicable. |
| Supplier | Apotex Corp. 2400 N. Commerce Parkway Suite 400 Weston, FLA 33326 Telephone: (954)384-8007 Toll Free: 1-800-706-5575 | Chemical structure | Not applicable |
| Material uses | Pharmaceutical industry: Dosage form Therapeutic category: Antidepressant | Manufacturer | Apotex Inc. 150 Signet Drive Weston, Ontario M9L 1T9 416-749-9300 |
| Emergency phone | United States/Canada (Chemtrec) 1-800-424-9300 or +1 703-527-3887 (24 hours) For general information call: 1-(416)-749-9300 ext. 8483 (8 AM-4 PM) | DIN | Not available. |

| Section 2. Hazards Identification | |
|--|--|
| Potential Acute Health Effects | Not expected to be hazardous under normal handling conditions. |
| Potential Chronic Health Effects | Possible hypersensitization. |
| Apotex Hazard Classification (For Apotex internal practices only) | This material has been assigned hazard class: 2 |

| Section 3. First Aid Measures | |
|--------------------------------------|--|
| Eye contact | Flush with copious quantities of water. If irritation persists, obtain medical advice. |
| Skin contact | Not expected to result in hazardous effects. |
| Hazardous skin contact | Flush with copious amounts of water. Seek medical attention if irritation persist. |
| Slight inhalation | Allow the victim to rest in a well ventilated area. If symptoms persist, obtain medical advice. |
| Hazardous 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. |
| Slight ingestion | Flush out mouth with water. Seek medical attention if irritation persists. |
| Hazardous 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. Treatment of overdose should be symptomatic and supportive and may include the following: 1. To empty stomach, perform gastric lavage. Ipecac-induced vomiting is NOT recommended. 2. Administer activated charcoal slurry followed by a stimulant cathartic. 3. Maintain respiratory and cardiac function. 4. Provide symptomatic and supportive treatment in the event of hypotension or excessive sedation. |

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5. Forced diuresis may be useful. (USP DI 2006)


Section 4. Hazardous Ingredients

| Name | CAS # | % (w/w) |
|--|------------------|---------|
| Trazodone hydrochloride | 25332-39-2 | 30-50 |
| Magnesium stearate | 557-04-0 | 1-10 |
| Toxicity values of the hazardous ingredients | | |
| Refer to Sec. 11. | | |
| TLV | Not established. | |

Section 5. Fire Fighting Measures

| | |
|-------------------------------|---|
| The product is: | May be combustible at high temperature. |
| Autoignition temperature | Not available. |
| Fire degradation products | Decomposition products may include the following materials: carbon dioxide, carbon monoxide, nitrogen oxides, halogenated compounds, metal oxide/oxides. |
| Flash points | Not available. |
| Flammable limits | Not available. |
| Fire extinguishing procedures | 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. |
| Flammability | Emits toxic fumes under fire conditions. |
| | Remark No additional remark. |
| Risks of explosion | Not available. |
| | Remark No additional remark. |

Section 6. Accidental Release Measures

| | |
|--|--|
| Spill and leak | Vacuum or sweep up spillage. Avoid dust. Place spillage into an appropriate labeled waste disposal container. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate Safe Work Practices. |
| Protective Clothing Pictograms in case of large spill and/or high exposure levels | |
| Protective clothing in case of large spill | Full facepiece Air Purifying Respirator with particulate cartridge P100 (HEPA). Gloves. Covering uniform. |
| |  |

Section 7. Handling and Storage

| | |
|-------------|--|
| Precautions | Avoid breathing dust. |
| Storage | Store at 20 to 25°C (68° to 77°F). Protect from light. |

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 When handling small quantity of the product with adequate ventilation, gloves are sufficient. Where a packaging process involves limited containment of open product, a half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridges, covering uniform and safety glasses are required.

Protective Clothing (Pictograms)



PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Respiratory protection may not be required in areas where a high degree of process containment exists. The respirator use limitations specified by the approving agency and the manufacturer must be observed. Refer to the CSA Standard Z94, "Selection, Care, and Use of Respirators". Have appropriate equipment available for use in emergencies such as spills or fire.
EYE/FACE PROTECTION : Safety glasses when working in dusty area.
SKIN PROTECTION : The use of nitrile gloves is required for Good Manufacturing Practices (GMP) compliance.
RESISTANCE OF MATERIALS FOR PROTECTIVE CLOTHING : Resistance of specific materials can vary from product to product. Evaluate resistance under conditions of use and maintain clothing carefully.
EXPOSURE CONTROLS/PERSONAL PROTECTION COMMENTS: In the event clothing becomes contaminated, remove promptly. Launder before use. Inform laundry personnel of contaminant's hazards. Do not eat, drink or smoke in work areas. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Section 9. Physical and Chemical Properties

Physical state and appearance 50 mg: white, round, biconvex tablets, scored and engraved "APO" bisect "T50" on one side, other side plain.
 100 mg: white, round, biconvex tablets, scored and engraved "APO" bisect "T100" on one side, other side plain.
 150 mg: white, oval, flat faced beveled-edge tablets with a full bisect and 2 partial trisects. Engraved "APO" bisect "T150" on one side, and "50 50 50" on the other side.
 300 mg: white, oval, flat faced beveled-edge tablets with a full bisect and 2 partial trisects. Engraved "APO" bisect "T300" on one side, and "100 100 100" on the other side with the middle "100" perpendicular to the others.

| | | | |
|--|-----------------------|--------------|----------------|
| pH | Not available. | Taste | Not available. |
| Odor threshold | Not available. | Odor | Not available. |
| Volatility | Not available. | | |
| Melting point/ Freezing point | Not available. | | |
| Boiling point | Not available. | | |
| Specific gravity | Not available. | | |
| Vapor density | Not available. | | |
| Vapor pressure | Not available. | | |
| Partition Coefficient: | Not available. | | |
| Ionicity (surface active agent) | Not available. | | |
| Critical temperature | Not available. | | |
| Instability temperature | Not available. | | |
| Conditions of instability | No additional remark. | | |
| Dispersion properties | See solubility. | | |
| Evaporation rate | Not available. | | |

Solubility Not available.

Section 10. Stability and Reactivity

Stability The product is stable.

Hazardous decomp. products Decomposition products may include the following materials: halogenated compounds, hydrogen chloride.

Degradability Not available.

Corrosivity Not corrosive

Remark

No additional remark.

Reactivity/Incompatibility Protect from light.

Remark

No additional remark.

Section 11. Toxicological Information

Routes of entry 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 Trazodone hydrochloride:
RTECS#: XZ5660000
TDLo: 667 micrograms/kg (oral-man)
TDLo: 43 mg/kg/30 Days intermittent (oral-man)
LD50: 690 mg/kg (oral-rat)
LD50: 584 mg/kg (oral-mouse)
Magnesium stearate:
LD50 (oral-rat): Greater than 10 g/kg body weight (25% magnesium stearate suspended in corn oil)

Long-term effects Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. No evidence of carcinogenicity was observed in rats receiving up to 300 mg/kg a day for 18 months.

Teratogenicity/Reproductive Toxicity: Pregnancy category C. There are no adequate and well-controlled studies of trazodone use in pregnant women. Congenital anomalies and fetal resorption were reported in animals receiving doses up to 50 times those used in humans.

Mutagenicity: No information available.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to the material, active alcoholism, recent heart attack, liver or kidney function impairment, and heart disease.

Short-term effects and Signs & Symptoms of overexposure Adverse effects may include blurred vision, dry mouth, dizziness, lightheadedness, drowsiness, nausea or vomiting, confusion, muscle tremors, constipation or diarrhea, muscle aches or pains, unusual tiredness or weakness, unpleasant taste, and headache. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects include drowsiness, loss of muscle coordination, nausea, vomiting, prolonged painful erection, respiratory arrest, and seizures.

Remark

The above adverse effects are based on clinical studies.

Section 12. Ecological Information

Ecological Information Not available.

Section 13. Disposal Considerations

Waste Disposal For internal Apotex waste disposal: Collect in sealed containers and place in appropriate labeled pharmaceutical solid waste class 261N.
For external waste disposal: Follow all appropriate safe work procedures and federal, provincial 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 |
|------------------------|-----------|----------------------|----------------|---------------|-------|------------------------|
| TDG- road Canada/U.S. | | | Not regulated. | | | |
| ICAO-Air | | | Not regulated. | | | |
| ADR | | | Not regulated. | | | |
| IMDG Class | | | Not regulated. | | | |

Section 15. Other Regulatory Information and Pictograms

WHMIS CLASS D-2A: Material causing other toxic effects (VERY TOXIC).



Remark

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

EU Classification and Labelling Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device. R40- Possible risks of irreversible effects.

Other Regulations

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

Section 16. Other Information

References RTECS Database
Meditext - Medical Management
Apotex Product Monograph

MSDS:
U.S. Pharmacopeia

Validation date:
(year.month)

Revision date: 9/24/2014. Apotex Inc.
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Weston (Toronto), Ontario
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