

SAFETY DATA SHEETS

This SDS packet was issued with item:

078931524

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078943584 078944181

Safety Data Sheet

Section 1. Identification

Common/Trade name : Apo-Sotalol Tablets; Sotalol Hydrochloride Tablets; Sotalol Hydrochloride Tablets (AF)

Recommended use : Pharmaceutical industry: Dosage form
Therapeutic category: Antiarrhythmic

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	U.S.
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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)

Section 2. Hazards Identification

Classification of the substance or mixture : TOXIC TO REPRODUCTION (Unborn child) - Category 2
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (cardiovascular system) - Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 - Suspected of damaging the unborn child.
H373 - May cause damage to organs through prolonged or repeated exposure. (cardiovascular system)

Precautionary statements

General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Do not breathe dust.

Response : Get medical attention if you feel unwell. If exposed or concerned: Get medical attention.

Storage : Store locked up.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/Information on Ingredients

Name	CAS #	%
Sotalol hydrochloride	959-24-0	40 - 70
Magnesium stearate	557-04-0	1 - 5

All other components are either non-hazardous or the concentrations are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication standard 29 CFR 1910.1200, and the European Directive 91/155/EEC, and 93/112/EC and the Hazardous Product Regulations under item 3(2) of Schedule I.

Chemical name : Not applicable.

Synonyms : Not available.

Chemical family : Ethanolamine

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 : Cordon off spill area as needed. Assess hazard levels (contact Safety Department if required). 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 : Personnel involved in clean up should wear appropriate personal protective equipment (refer to section 8) to avoid exposure.

Section 7. Handling and Storage

- Precautions for safe handling** : Handle in an environment with adequate ventilation. In case of insufficient ventilation, wear suitable respiratory protection. Avoid inhalation, skin and eye contact. Wash hands thoroughly after handling.
- Conditions for safe storage** : Store as directed by product packaging/manufacturer's requirements.

Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : Airborne exposure to this material should be mitigated using engineering controls such as mechanical ventilation, dilution and process enclosure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Local exhaust ventilation (e.g. fume hoods or other vented enclosures) is recommended, particularly for crushing, grinding or other activities prone to generating dust or aerosols.
- Personal Protection** : **For Manufacturing Environments:**
- Skin: Covering uniform
- Respiratory: Where respiratory protection has been deemed necessary use an approved air purifying respirator with appropriate cartridges. Contact your local safety professional for specific requirements.
- Hand: Nitrile or other chemically compatible gloves.
- Eye: Safety glasses
- For all other environments (Laboratories, hospitals, pharmacies, etc.):**
- Skin: Lab coat
- Respiratory: 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, breakage, generation of aerosols or for spill cleaning, an approved respirator may be required. Contact your local safety professional for specific requirements.
- Hand: Nitrile or other chemically compatible gloves.
- Eye: Safety glasses
- Occupational exposure limits** : Not established.

Section 9. Physical and Chemical Properties

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|--------------------------------------|------------------|----------------------------------|-------------------------|
| Physical state and appearance | : Tablets. | | |
| pH | : Not available. | Odor | : Not available. |
| Melting point/Freezing point | : Not available. | Odor threshold | : Not available. |
| Boiling point | : Not available. | Conditions of instability | : No additional remark. |
| Volatility | : Not available. | Decomposition temperature | : Not available. |
| Specific gravity | : Not available. | Partition Coefficient: | : Not available. |
| Evaporation rate | : Not available. | Viscosity | : Not available. |
| Vapor density | : Not available. | Flash points | : Not applicable. |
| Relative density | : Not available. | Flammable limits | : Not available. |
| Vapor pressure | : 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 : Sotalol:

LD50: 3450 mg/kg (oral-rat)
LD50: 2600 mg/kg (oral-mouse)

Magnesium stearate:

LD50: >10000 mg/kg (oral-rat)

Delayed and immediate effects and also chronic effects from short and long term exposure : Carcinogenicity: No evidence of carcinogenic potential was observed in rats during a 24-month study at 137-275 mg/kg/day (approximately 30 times the maximum recommended human oral dose (MRHD) as mg/kg or 5 times the MRHD as mg/m²) or in mice, during a 24-month study at 4141-7122 mg/kg/ day (approximately 450-750 times the MRHD as mg/kg or 36-63 times the MRHD as mg/m²).

Teratogenicity: Pregnancy Category B: In rabbits, a high dose of Sotalol HCl (160 mg/kg/day) at 16 times the MRHD as mg/kg (6 times the MRHD as mg/m²) produced a slight increase in fetal death, and maternal toxicity. Reproduction studies in rats and rabbits during organogenesis at 100 and 22 times the MRHD as mg/kg (9 and 7 times the MRHD as mg/m²), respectively, did not reveal any teratogenic potential associated with Sotalol HCl.

Mutagenicity: Sotalol was not genotoxic in Ames assay.

Remark

No additional remark.

Symptoms related to the physical, chemical and toxicological characteristics : The most common adverse effects seen at therapeutic doses include: bradycardia, chest pain, palpitations, fatigue, dizziness, lightheadedness, weakness, and dyspnea. Other less common adverse effects include edema, hypotension, syncope, congestive heart failure, torsades de pointes, peripheral vascular disorders, headaches, sleeping problems, mental confusion, anxiety, depression, pruritus, rash, decreased sexual ability, nausea and/or vomiting, diarrhea, abdominal discomfort, flatulence, impotence, bleeding, extremity pain, paresthesia, back pain, visual problems, upper respiratory problems, and asthma.

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	Additional information
TDG- road Canada/U.S.			Not regulated.		
ICAO/IATA			Not regulated.		
IMDG Class			Not regulated.		

Section 15. Regulatory Information

Canada Regulations : Not listed on the Domestic Substances List (DSL).

Other Regulations : Not available.

Section 16. Other Information

Revision date: 12/5/2018

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.