

Sotalol hydrochloride

sc-203699

Material Safety Data Sheet



The Power is Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Sotalol hydrochloride

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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EMERGENCY

ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C12-H20-N2-O3-S.HCl, CH3SO2NHC6H4C(OH)CNHC(CH3)2.HCl, "methanesulfonanilide, 4' -[1-hydroxy-2-(isopropylamino)ethyl]-, ", hydrochloride, "4' -[1-hydroxy-2-(isopropylamino)ethyl]methanesulfonanilide", monohydrochloride, "N-[4-(1-hydroxy-2-((1-(methylethyl)amino)ethyl)phenyl methanesulfonamide", "isopropylaminohydroxyethylmethanesulfonamide hydrochloride", d-sotalol, Beta-Cardone, Betacardone, Betapace, Bedades, Darob, "Mead Johnson 1999", MJ-1999, MJ-5763-1, Sotacor, Sotalex, Sotapor, Tolerzide, "beta-adrenoreceptor blocker"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	3		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Harmful if swallowed.

Irritating to eyes, respiratory system and skin.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

■ Sulfonamides and their derivatives can cause extensive kidney damage, and destroy red blood cells.

Overdose may cause an accumulation of acid in the blood or a diminished blood sugar level with confusion and coma resulting.

■ Side effects from beta-locking agents include nausea, vomiting, disturbance of the gastrointestinal tract, fatigue and dizziness.

The nervous system may be involved, causing depression, delirium, stoppage of breathing, confusion, psychosis, motor abnormalities, coma, visual disturbance and insomnia.

EYE

■ This material can cause eye irritation and damage in some persons.

■ Eye drops with sulfonamides can cause local irritation, sensations of burning and stinging, blurred vision and loss of depth perception.

The conjunctiva and cornea may become inflamed, and the cornea and lens may become clouded.

■ Eye absorption of beta blockers can reduce the pressure in the eye and causes systemic toxicity.

SKIN

■ This material can cause inflammation of the skin on contact in some persons.

■ The material may accentuate any pre-existing dermatitis condition.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material can cause respiratory irritation in some persons.

The body's response to such irritation can cause further lung damage.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is some evidence to provide a presumption that human exposure to the material may result in impaired fertility on the basis of: some evidence in animal studies of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary non-specific consequence of other toxic effects.

Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, on the basis that similar materials tested in appropriate animal studies provide some suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.

Prolonged oral treatment with sulfonamides has caused nausea, vomiting, diarrhea, abdominal pain, loss of appetite, inflammation of the mouth cavity, impaired folic acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas. Effects on the kidney include blood and crystals in the urine, painful and frequent urination or lack of urine with nitrogen retention.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

Prolonged use of beta blockers can result in dry mouth, taste distortion, heartburn, stomach pain, nausea, vomiting, loss of appetite, bloating, flatulence, and diarrhea or constipation. The nervous system may be affected by fatigue, headache, dizziness, lethargy, depression, "pins and needles", reduced or increased sensation, anxiety, nervousness, poor concentration, sleep loss and nightmares or bizarre dreams.

No evidence of carcinogenic potential was seen in a 24-month study in rats receiving about 30 times the maximum human oral dose (as mg/kg) or in mice receiving 450-750 times the maximum human oral dose (as mg/kg).

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
sotalol hydrochloride	959-24-0	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

■ Following a recent overdosage with a beta-blocker the stomach should be emptied by gastric lavage. Emesis should not be used. Almost completely absorbed from the gastrointestinal tract and excreted in the urine unchanged. The material is not bound to plasma proteins; crosses the placenta, and is found in breast milk. Because of the lack of protein binding, haemodialysis is useful for reducing plasma concentrations. Patients should be carefully observed until QT intervals are normalised and the heart rate returns to levels greater than 50 beats per minute. In addition, if required, the following therapeutic measures are suggested. Bradycardia or cardiac asystole: Atropine, another anticholinergic drug, a beta-adrenergic agonist or transvenous cardiac pacing. Heart Block (second and third degree): transvenous cardiac pacemaker. Hypotension (depending on associated factors): epinephrine rather than isoproterenol or norepinephrine may be useful. Bronchospasm: Aminophylline or aerosol beta-2-receptor stimulant. Sotalol is contraindicated in patients with bronchial asthma, sinus bradycardia, second and third degree AV block, unless a functioning pacemaker is present, congenital or acquired long QT syndromes, cardiogenic shock, uncontrolled congestive heart failure and previous evidence of hypersensitivity to the drug. Physicians Desk Reference (PDR) Electronic Library:

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

· Water spray or fog.
· Foam.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited. Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen chloride, phosgene, nitrogen oxides (NO_x), sulfur oxides (SO_x), other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes. Dust Explosion Hazard Class 1
Dusts fall into one of three Kst* classes. Class 1 dusts; Kst 1-200 m³/sec; Class 2 dusts; 201-299 m³/sec. Explosion data relative to mechanical impact: Not tested. Handle to prevent damage to the container during shipment. Explosion data relative to static discharge: Explosion Severity Factor (Kst): 174 bar.m/s
Explosion Class: ST-1
Minimum Ignition Energy: 80-90 millijoules
Resistivity: 7.3 ee 10 ohm.m
Charge decay time: <1 sec
Material exhibits weak to moderate explosion characteristics if ignited as a dust cloud. Material is moderately susceptible to the accumulation of static charge during processing; uncontrolled static discharge may result in ignition of a dust cloud under certain conditions due to low minimum ignition energy. Provide suitable bonding and grounding for containers and process equipment to control static charges. Powder handling equipment such as dust collectors, dryers and mills may require additional protective devices such as explosion venting.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
 - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
 - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Store in original containers.
 - Keep containers securely sealed.
- NOTE: Store in the dark.

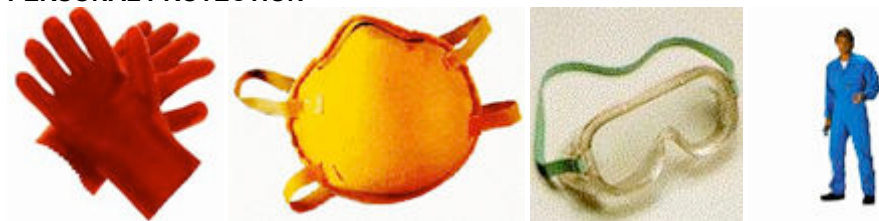
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- sotalol hydrochloride: CAS:959-24-0

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

- When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
- frequency and duration of contact,

- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.

· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.

· Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

· Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.

· Double gloving should be considered.

· PVC gloves.

· Protective shoe covers.

· Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

· polychloroprene

· nitrile rubber

· butyl rubber

· fluorocautchouc

· polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

· For quantities up to 500 grams a laboratory coat may be suitable.

· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.

· For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

· For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

· Eye wash unit.

· Ensure there is ready access to an emergency shower.

· For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Assess operations based upon available dust explosion information to determine the suitability of preventative or protective systems as precautionary measures against possible dust explosions. If prevention is not possible, consider protection by use of containment, venting or suppression of dust handling equipment. Where explosion venting is considered to be the most appropriate method of protection, vent areas should preferably be calculated based on K_{st} rather than an St value. If nitrogen purging is considered as the protective system, it must operate with an oxygen level below the limiting oxygen concentration. The system should include an oxygen monitoring and shut-down facility in the event of excessive oxygen being detected.

The maximum surface temperature of enclosures potentially exposed to this material should be based on values obtained by taking 2/3 of the minimum ignition temperature (MIE) of the dust cloud. The effect of dust layers should be reviewed.

An isolated (insulated) human body can readily produce electrostatic discharges in excess of 50 mJ, but have been recorded up to 100 mJ.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	308.82
Melting Range (°F)	395.6- 397.4;218-219	Viscosity	Not Applicable
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

APPEARANCE

White crystalline solid; mixes with water, propylene glycol, ethanol. Sotalol hydrochloride is a racemic mixture of d- and l-forms.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

SOTALOL HYDROCHLORIDE

TOXICITY AND IRRITATION

SOTALOL HYDROCHLORIDE:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (man) LDLo: 45.7 mg/kg	Nil Reported
Oral (rat) LD50: 3450 mg/kg	
Intraperitoneal (rat) LD50: 680 mg/kg	
Oral (mouse) LD50: 2600 mg/kg	
Intraperitoneal (mouse) LD50: 670 mg/kg	
Intraperitoneal (dog) LD50: 330 mg/kg	

Oral (rabbit) LD50: 1000 mg/kg

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Convulsions, excitement, dyspnea, cardiac arrhythmias, ptosis, somnolence, ataxia, changes in motor activity, changes in liver weight, weight loss/ decreased weight gain, death, changes in heart weight, increased urine volume, changes in spleen weight, maternal effects, effects on newborn, paternal effects, effects on fertility, foetolethality recorded.

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

! Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

sotalol hydrochloride (CAS: 959-24-0) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)", "OECD Representative List of High Production Volume (HPV) Chemicals"

Section 16 - OTHER INFORMATION

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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