

# Sotalol hydrochloride

## Safety Data Sheet

**900120**

Version: 3.1

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 08/12/2014 Revision date 28/11/2019  
Supersedes 14/08/2019

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Substance  
Substance name : Sotalol hydrochloride  
CAS-No. : 959-24-0  
Product code : 900120  
Formula : C<sub>12</sub>H<sub>21</sub>CIN<sub>2</sub>O<sub>3</sub>S  
Product group : Raw material

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry  
Industrial/Professional use spec : Industrial  
For professional use only  
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Duchefa Farma BV  
A. Hofmanweg 71  
2031BH Haarlem - Nederland  
T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

#### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
+31(0)23-5319093 (M-F 09:00-17:00)  
+31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2 H315  
Serious eye damage/eye irritation, Category 2 H319

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Specific target organ toxicity — Single exposure, Category 3, H335  
Respiratory tract irritation

Full text of H statements : see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display  
classification(s) to display

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P280 - Wear protective gloves/protective clothing/eye  
protection/face protection.  
P302+P352 - IF ON SKIN: Wash with plenty of water/...  
P304+P340 - IF INHALED: Remove person to fresh air and keep  
comfortable for breathing.  
P305+P351 - IF IN EYES: Rinse cautiously with water for several  
minutes.

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sotalol hydrochloride	(CAS-No.) 959-24-0	99 - 101	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell. If breathing is difficult, give oxygen.
First-aid measures after skin contact	: Wash with plenty of water/... Wash contaminated clothing before reuse. If skin irritation occurs: Immediately call a POISON CENTER/doctor Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth Do NOT induce vomiting. Obtain emergency medical attention.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Foam Dry powder Carbon dioxide Water spray Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

Reactivity in case of fire	: release of harmful gases/vapours.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO <sub>2</sub> ) Nitrous fumes Sulphur oxides Hydrogen chloride.

### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin and eyes.

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Residue may be washed down with water. Minimise generation of dust. Store away from other materials.

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container in a cool, well ventilated place  
away from : Protect from light  
Keep out of frost  
Keep container tightly closed.
- Incompatible products : Strong bases. Strong acids.
- Incompatible materials : Sources of ignition. Direct sunlight.
- Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

Pharmaceutical industry.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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Additional information : Open handling may result in overexposure and spread of contamination.

## 8.2. Exposure controls

### Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

### Personal protective equipment:

Protective clothing. Gloves. Safety glasses. Dust/aerosol mask with filter type P2.

### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

### Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

### Respiratory protection:

Dustmask with filtertype P2



## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 308.82 g/mol
Colour	: White to off-white.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 210 - 215 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available

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Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water Soluble in ethanol Soluble in dichloromethane.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Not established.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight

Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong bases

Oxidizing agents

stainless steel.

### 10.6. Hazardous decomposition products

Carbon monoxide

Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Sotalol hydrochloride (959-24-0)	
LD50 oral rat	3450 mg/kg
LD50 oral	2600 mg/kg mouse
LD50 dermal rat	680 mg/kg intraperitoneal
LD50 dermal	670 mg/kg mouse intraperitoneal
LDLo (oral, man)	45.7 mg / kg
LD 50 oral (Rabbit)	1000 mg/kg
Additional information	nil reported

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: May be harmful if inhaled. Irritation of the respiratory tract
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

<b>Sotalol hydrochloride (959-24-0)</b>	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

<b>Sotalol hydrochloride (959-24-0)</b>	
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

<b>Sotalol hydrochloride (959-24-0)</b>	
Mobility in soil	≈

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

### 14.6. Special precautions for user

#### . Overland transport

No data available

#### - Air transport

No data available

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Sotalol hydrochloride is not on the REACH Candidate List

Sotalol hydrochloride is not on the REACH Annex XIV List

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:

1		Modified	Change of Logo
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Full text of H- and EUH-statements:

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Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*