

Page 1/8

## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

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

· Product identifier

· Trade name: Sotalol hydrochloride, API

· Article number: 5575

• **CAS Number:** 959-24-0

• **EC number:** 213-496-0

- · Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

- · Uses advised against No relevant information available.
- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

**CAELO** 

Caesar & Loretz GmbH

Herderstr. 31

D-40721 Hilden

**GERMANY** 

#### · Further information obtainable from:

E-mail: info@caelo.de

Tel.: +49210349940 (during regular opening hours)

· Emergency telephone number:

Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn

Tel: +49 (0) 228-192400

### 2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

- · Label elements
- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)



Page 2/8

# Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 1)

#### · Hazard pictograms



· Signal word Warning

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation. H335 May cause respiratory irritation.

**Precautionary statements** 

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P280 Wear eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Other hazards

- · Results of PBT and vPvB assessment
- PBT: Not applicable.vPvB: Not applicable.
- · Determination of endocrine-disrupting properties Not applicable.

#### 3 Composition/information on ingredients

- · Substances
- · CAS No. Description

CAS: 959-24-0 4'-(1-hydroxy-2-isopropylaminoethyl)methanesulfonanilide hydrochloride

- · Identification number(s)
- EC number: 213-496-0

#### 4 First aid measures

- · Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: If symptoms persist consult doctor.
- Most important symptoms and effects, both acute and delayed

No further relevant information available.

(Contd. on page 3)



Page 3/8

## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 2)

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

#### 5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · Advice for firefighters
- · Protective equipment: In case of fire wear suitable protective clothes and respiratory protection.
- · Additional information

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

#### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Avoid contact with the substance.

- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Take up dry. Clean up with water.

Dispose contaminated material as waste according to section 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### 7 Handling and storage

- · Precautions for safe handling Provide suction extractors if dust is formed.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles:

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: No further information
- · Storage class: TRHS 510: 11 Combustible solids
- · Specific end use(s) No further relevant information available.

## 8 Exposure controls/personal protection

- · Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.

(Contd. on page 4)



Page 4/8

## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 3)

- · Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- Respiratory protection: Dust protection mask.
- Hand protection Protective gloves
- Material of gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye/face protection Tightly sealed goggles
- · Body protection: Protective work clothing

#### 9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:

Solid
White
Odourless
Not determined.
Undetermined.

Boiling point or initial boiling point and boiling

range Undetermined.

· Flammability Product is not flammable.

Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.

· **pH** 5–6

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

• water at 20 °C: 782 g/l

Partition coefficient n-octanol/water (log value)
 Vapour pressure:
 Not determined.
 Not applicable.

(Contd. on page 5)



Page 5/8

## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 4)

· Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Vapour density Not applicable.
 Particle characteristics See section 3.

· Other information

· Appearance:

· **Form:** Crystalline powder

Important information on protection of health

and environment, and on safety.

· **Ignition temperature:** Not determined.

• **Explosive properties:** Product does not present an explosion hazard.

Void

Void Void

Void

Void

Void

· Change in condition

• Evaporation rate Not applicable.

Information with regard to physical hazard

classes
Explosives
Flammable gases
Aerosols
Oxidising gases
Gases under pressure
Flammable liquids

· Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void Oxidising liquids Void · Oxidising solids Void Void

· Organic peroxides Void
· Corrosive to metals Void
· Desensitised explosives Void

#### 10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

(Contd. on page 6)



Page 6/8

## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 5)

### 11 Toxicological information

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure May cause respiratory irritation.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Information on other hazards
- · Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

#### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- **Endocrine disrupting properties**

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

The product does not contain substances with endocrine disrupting properties.

- Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

(Contd. on page 7)



Page 7/8

# Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 1.00 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 6)

### 13 Disposal considerations

- · Waste treatment methods
- Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to local regulations.

### \*14 Transport information

· **UN number or ID number**Not subject to transport regulations.

ADR, IMDG, IATA not regulated

· UN proper shipping name

ADR not regulated not regulated

· Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class not regulated

· Packing group

ADR, IMDG, IATA not regulated
 Environmental hazards: Not applicable.
 Special precautions for user Not applicable.

· Maritime transport in bulk according to IMO

instruments Not applicable.
UN "Model Regulation": not regulated

#### 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- · REGULATION (EC) No 1907/2006 ANNEX XVII Not listed
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

Substance is not listed.

- · National regulations:
- Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 11 Combustible solids

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### 16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- Reasons for alterations This version replaces all old versions.
- Date of previous version: 23.09.2025
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

(Contd. on page 8)



Page 8/8

## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Version number 1.00 Printing date 23.09.2025 Revision: 23.09.2025

Trade name: Sotalol hydrochloride, API

(Contd. of page 7)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

\* Data compared to the previous version altered.

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