



SAFETY DATA SHEET

SOTALOL HYDROCHLORIDE

1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name : SOTALOL HYDROCHLORIDE
Product code : 15782.SOT
Identification of the product : N-[4-[1-Hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl] methanesulfonamide hydrochloride
CAS No :000959-24-0
EC No :213-496-0
Annex No :---
REACH Ref. :---
Chemical formula : C₁₂H₂₀N₂O₃S.HCl
SMILE : CC(C)NCC(O)C1=CC=C(NS(C)(=O)=O)C=C1 (Sotalol Base)
RTECS nr : No data available.

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

Use : Pharmaceutical industry.

2. Hazards identification**2.1. Classification of the substance or mixture****Classification EC 67/548 or EC 1999/45**

Classification : Xi; R36/37/38

Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

2. Hazards identification (continued)

Health hazards : Skin irritation - Category 2 - Warning (CLP : Skin Corr. 2) H315
 Eye irritation - Category 2A - Warning (CLP : Eye Irrit. 2) H319
 Specific Target Organ Toxicity - Single exposure - Respiratory tract irritation - Category 3 - Warning (CLP : STOT SE 3) H335

2.2. Label elements

Labelling EC 67/548 or EC 1999/45

Symbol(s)



Symbol(s) : Xi : Irritant
R Phrase(s) : R36/37/38 : Irritating to eyes, respiratory system and skin.
S Phrase(s) : S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 S36 : Wear suitable protective clothing.
Contains : N-[4-[1-Hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl] methanesulfonamide hydrochloride

Labelling Regulation EC 1272/2008 (CLP)

Hazard pictograms



Signal words : Warning
Hazard statements : H319 : Causes serious eye irritation.
 H315 : Causes skin irritation.
 H335 : May cause respiratory irritation.
Precautionary statements
 • **General** : P102: Keep out of reach of children.
 • **Prevention** : P280: Wear protective gloves, protective clothing, eye protection, face protection.
 P271: Use only outdoors or in a well-ventilated area.
 P261: Avoid breathing dust, fume, gas, mist, vapours, spray.
 P264: Wash thoroughly after handling.
 • **Response** : P304+P340: IF INHALED : Remove to fresh air and keep at rest in a position comfortable for breathing.
 P302+P352: IF ON SKIN : Wash with plenty of soap and water.
 P305+P351+P338: IF IN EYES : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337+P313: If eye irritation persists: Get medical advice/attention.
 P332+P313: If skin irritation occurs : Get medical advice.
 • **Storage** : P233: Keep container tightly closed.
 P235: Keep cool.
 P405: Store locked up.



2. Hazards identification (continued)

- **Disposal considerations** : P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
- Contains** : N-[4-[1-Hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl] methanesulfonamide hydrochloride

2.3. Other hazards

- Other hazards** : None under normal conditions.

3. Composition/information on ingredients

- Substance / Preparation** : Substance.
N-[4-[1-Hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl] methanesulfonamide hydrochloride
CAS No :000959-24-0
EC No :213-496-0
Annex No :---
REACH Ref. :---
- Molecular Formula** : C₁₂H₂₀N₂O₃S.HCl
- Synonymous** : Methanesulfonanilide, 4'-[1-hydroxy-2-(isopropylamino)ethyl]-, monohydrochloride ;
N-[4-[1-hydroxy-2-(propan-2-ylamino)ethyl]phenyl]methanesulfonamide hydrochloride ; Sotalol HCl
- Hazardous component(s)** : This product is hazardous.

| Substance name | Contents | CAS No | EC No | Annex No | REACH Ref. | Classification |
|--|----------|----------|-----------|----------|------------|--|
| N-[4-[1-Hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl] methanesulfonamide hydrochloride | 100 % | 959-24-0 | 213-496-0 | --- | --- | Xi, R36/37/38 Eye Irrit 2 Skin Irrit. 2 STOT SE 3 |

Contains no other components or impurities which will influence the classification of the product.

4. First aid measures

4.1. Description of first aid measures

- Inhalation** : Call a POISON CENTER or doctor if you feel unwell. Remove to fresh air and keep at rest in a position comfortable for breathing.
- Skin contact** : If skin irritation occurs : Wash with plenty of soap and water. Wash contaminated clothing before reuse. Get medical advice. Specific treatment (see on this label).
IF ON SKIN : Wash with plenty of soap and water. Take off contaminated clothing and wash before reuse. If skin irritation occurs : Get medical advice. Specific treatment.
- Eye contact** : Rinse cautiously with water for several minutes.
IF IN EYES : 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. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists : Get medical advice.
- Ingestion** : Do not induce vomiting. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.



4. First aid measures (continued)

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

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

General information : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting measures

5.1. Extinguishing media

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

Unsuitable extinguishing media : Do not use a heavy water stream.

Surrounding fires : Use water spray or fog for cooling exposed containers.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Under fire conditions, hazardous fumes will be present.

5.3. Advice for fire-fighters

Protection against fire : Do not enter fire area without proper protective equipment, including respiratory protection.

Special procedures : Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For emergency responders : Equip cleanup crew with proper protection.

For non-emergency personnel : Evacuate unnecessary personnel.

6.2. Environmental precautions

Environmental precautions : Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Clean up methods : Ventilate area. On land, sweep or shovel into suitable containers. Minimize generation of dust.

6.4. Reference to other sections



6. Accidental release measures (continued)

See section 8. Exposure controls/personal protection

7. Handling and storage

7.1. Precautions for safe handling

| | |
|-------------------------------|--|
| Handling | : Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. |
| Special precautions | : Avoid breathing dust, fume, gas, mist, vapours, spray. |
| Technical protective measures | : Provide good ventilation in process area to prevent formation of vapour. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---------------------|---|
| Storage | : Keep only in the original container in a cool, well ventilated place. Keep container tightly closed. Store at room temperature. |
| Storage - away from | : Strong bases. Strong acids. Sources of ignition. Direct sunlight. |

7.3. Specific end use(s)

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|---------------------|---------|
| Specific end use(s) | : None. |
|---------------------|---------|

8. Exposure controls/personal protection

8.1. Exposure controls

Personal protection



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| Personal protection | : Avoid all unnecessary exposure. |
| • Respiratory protection | : Where excessive dust may result, wear approved mask. |
| • Hand protection | : Wear protective gloves. |
| • Skin protection | : Wear suitable protective clothing. |
| • Eye protection | : Chemical goggles or safety glasses. |
| • Others | : When using, do not eat, drink or smoke. |

8.2. Control parameters

| | |
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| Occupational Exposure Limits | : No data available. |
|------------------------------|----------------------|

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties



9. Physical and chemical properties (continued)

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|-----------------------------------|---|
| Physical state at 20 °C | : Powder. |
| Molecular weight | : 308.86 (g/mol) |
| Colour | : White. |
| Odour | : Characteristic. |
| Odour threshold | : No data available. |
| pH value | : 4.5 - 5.6 (1% aq. sol.) 4 - 5 (5% aq. sol.) |
| Melting point [°C] | : 205 - 215 |
| Flash point [°C] | : 221.9 |
| Initial boiling point [°C] | : 443.3 (at 760 mmHg) |
| Density [g/cm ³] | : No data available. |
| Bulk density [kg/m ³] | : 500 |
| Solubility in water | : No data available. |
| Log P octanol / water at 20°C | : 0.85 Predicted using ALOGPS |

9.2. Other information

Explosive properties

| | |
|---|--------|
| • Layer minimum flammability temperature | : Melt |
| • Cloud minimum flammability temperature [°C] | : 510 |
| • Minimum ignition energy [mJ] | : 17 |
| - Explosion Class | : St1 |
| • Minimum explosive concentration [g/m ³] | : 30 |
| • Explosivity Pmax [bar·g] | : 7.6 |
| • Explosión severity factor Kmax [bar·m/s] | : 136 |

10. Stability and reactivity

10.1. Reactivity

| | |
|------------|--------------------|
| Reactivity | : Not established. |
|------------|--------------------|

10.2. Chemical stability

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|--------------------|--|
| Chemical stability | : Stable under recommended storage conditions. |
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10.3. Possibility of hazardous reactions

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|---------------------|--------------------|
| Hazardous reactions | : Not established. |
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10.4. Conditions to avoid



10. Stability and reactivity (continued)

Conditions to avoid : Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Materials to avoid : Strong acids. Strong bases.

10.6. Hazardous decomposition products

Hazardous decomposition products : On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides. Fumes.

11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

- Inhalation : Based on available data, the classification criteria are not met.
- Dermal : Based on available data, the classification criteria are not met.
 - Rat intraperitoneal LD50 [mg/kg] : 680
- Mouse intraperitoneal LD50 [mg/kg] : 670
- Ingestion : Based on available data, the classification criteria are not met.
 - Mouse oral LD50 [mg/kg] : 2600
 - Rat oral LD50 [mg/kg] : 3450
 - LD50 Rabbit oral [mg/kg] : 1000
- Other : Based on available data, the classification criteria are not met.

Corrosion : Based on available data, the classification criteria are not met.

Irritation : Causes serious eye irritation.
Causes skin irritation.
May cause respiratory irritation.

Sensitization : Based on available data, the classification criteria are not met.

Mutagenicity : No data available.

Carcinogenicity : No data available.

Toxic for reproduction : Based on available data, the classification criteria are not met.

STOT-single exposure : Based on available data, the classification criteria are not met.

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.

12. Ecological information

12.1. Toxicity

Toxicity information : Not established.

48 Hour-EC50 - Daphnia magna [mg/l] : 65



12. Ecological information (continued)

12.2. Persistence - degradability

Persistence - degradability : No data available.
Biodegradation [%] : No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential : No data available.

12.4. Mobility in soil

Mobility in soil : Not established.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

12.6. Other adverse effects

Environmental precautions : Avoid release to the environment.

13. Disposal considerations

13.1. Waste treatment methods

General : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.

14. Transport information

14.1. Land transport (ADR-RID)

General information : Not regulated.

14.2. Sea transport (IMDG) [English only]

General information : Not regulated.

14.3. Air transport (ICAO-IATA) [English only]

General information : Not regulated.



15. Regulatory information

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

Safety, health and environmental regulations/legislation specific for the substance or mixture : Ensure all national/local regulations are observed.

15.2. Chemical Safety Assessment

Chemical Safety Assessment : It has not been carried out.

16. Other information

| | |
|---|--|
| Revision | : Revision - See : * |
| Abbreviations and acronyms | : PBT: persistent, bioaccumulative and toxic. vPvB: very persistent and very bioaccumulative |
| Sources of key data used | : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 |
| List of relevant R phrases (heading 3) | : R36/37/38 : Irritating to eyes, respiratory system and skin. |
| List of full text of H-statements in section 3 | : H319 : Causes serious eye irritation. H315 : Causes skin irritation. H335 : May cause respiratory irritation. |
| Use | : Active Ingredient for Medicinal / pharmaceutical use. |
| Therapeutic Category | : Antianginal; antiarrhythmic; antihypertensive. |
| Further information | : See product bulletin for detailed information. |

The contents and format of this SDS are in accordance with REACH Regulation (CE) N° 1907/2006.

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