

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 03/04/2023 Revision date: 02/07/2025 Supersedes version of: 25/04/2025 Version: 3.0

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

### 1.1. Product identifier

Product form : Substance  
Substance name : Bisoprolol for system suitability  
Chemical name : Bisoprolol fumarate  
CAS-No. : 104344-23-2  
Product code : 201600111

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

#### Relevant identified uses

Use of the substance/mixture : Scientific research and development  
Technical testing and analysis  
For professional use only  
Function or use category : Laboratory chemicals

#### Uses advised against

Restrictions on use : Not for food, drug or home use

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

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4 H302  
Reproductive toxicity, Category 2 H361  
Specific target organ toxicity – single exposure, Category 1 H370  
Full text of H- and EUH-statements: see section 16

#### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Suspected of damaging fertility or the unborn child. Causes damage to organs.

### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H302 - Harmful if swallowed.  
H361 - Suspected of damaging fertility or the unborn child.  
H370 - Causes damage to organs (cardiovascular system).

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Precautionary statements (CLP)

- : P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
- P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
- P321 - Specific treatment (see supplemental first aid instruction on this label).
- P330 - Rinse mouth.
- P405 - Store locked up.
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

### Hazard pictograms (CLP)



GHS08

### 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]
Bisoprolol fumarate	CAS-No.: 104344-23-2	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=940 mg/kg bodyweight) Repr. 2, H361 STOT SE 1, H370

Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

No additional information available

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

No additional information available

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
- Unsuitable extinguishing media : Do not use a heavy water stream.

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

- Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

#### 5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

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

- General measures : Avoid contact with skin, eyes and clothing.
- For non-emergency personnel**
- Emergency procedures : Evacuate unnecessary personnel.
- For emergency responders**
- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

- For containment : Absorb with an inert material and place in an appropriate waste disposal container.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

#### 6.4. Reference to other sections

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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

- Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
- Packaging materials : Keep in original containers.

#### 7.3. Specific end use(s)

No additional information available

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

##### Appropriate engineering controls

###### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

##### Personal protection equipment

###### Eye and face protection

###### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

###### Skin protection

###### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

###### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

###### Respiratory protection

###### Respiratory protection:

In case of dust formation use respirator with filter: P3

### SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white, almost white.
Appearance	: Crystalline powder.
Molecular mass	: 766.96 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 100 – 103 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 6 – 7 (50 g/l)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: > 1000 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

#### 9.2. Other information

No additional information available

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

No additional information available

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

No additional information available

#### 10.6. Hazardous decomposition products

No additional information available

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

#### Bisoprolol fumarate (104344-23-2)

LD50 oral rat	940 mg/kg (RTECS No: UB8390000)
Skin corrosion/irritation	: Not classified (Lack of data) pH: 6 – 7 (50 g/l)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 6 – 7 (50 g/l)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Causes damage to organs (cardiovascular system).
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Lack of data)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Lack of data)

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 12.2. Persistence and degradability

#### Bisoprolol fumarate (104344-23-2)

Persistence and degradability	Not rapidly degradable
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### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not regulated for transport		
<b>14.2. UN proper shipping name</b>		
Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>		
Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>		
Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>		
Not regulated	Not regulated	Not regulated
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Air transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	<b>Modified</b>
	Revision date	<b>Modified</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Modified</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.2	Precautionary statements (CLP)	<b>Modified</b>
9	Melting point	<b>Added</b>
9	Molecular mass	<b>Added</b>
9	Colour	<b>Added</b>
9	Appearance	<b>Added</b>

# Bisoprolol for system suitability

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
11.1	LD50 oral rat	Modified

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.
H361	Suspected of damaging fertility or the unborn child.
H370	Causes damage to organs (cardiovascular system).
Repr. 2	Reproductive toxicity, Category 2
STOT SE 1	Specific target organ toxicity – single exposure, Category 1

Safety Data Sheet (SDS), EU

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