

Betaxolol hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 23/01/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Betaxolol hydrochloride
Chemical name : Betaxolol hydrochloride
EC-No. : 264-384-3
CAS-No. : 63659-19-8
Product code : 201600104

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, 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
Serious eye damage/eye irritation, Category 2 H319
Reproductive toxicity, Category 2 H361d
Reproductive toxicity, Additional category, Effects on or via lactation H362
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Harmful to aquatic life with long lasting effects. Suspected of damaging the unborn child. May cause harm to breast-fed children. Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :



Betaxolol hydrochloride

Safety Data Sheet

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

	GHS07	GHS08
Signal word (CLP)	: Warning	
Hazard statements (CLP)	: H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H361d - Suspected of damaging the unborn child. H362 - May cause harm to breast-fed children. H412 - Harmful to aquatic life with long lasting effects.	
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. P263 - Avoid contact during pregnancy and while nursing. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P273 - Avoid release to the environment. 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. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 - IF exposed or concerned: Get medical advice/attention. P330 - Rinse mouth. P337+P313 - If eye irritation persists: Get medical advice/attention. 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

Other hazards which do not result in classification	: Cardiac and blood circulation effects.
Other information	: Active substance (in pharmaceutical products/Pharmaceutical product used as cardiovascular drug). Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Betaxolol hydrochloride	CAS-No.: 63659-19-8 EC-No.: 264--384-3	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=998 mg/kg bodyweight) Eye Irrit. 2, H319 Repr. 2, H361d Lact., H362 Aquatic Chronic 3, H412

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.
----------------------------	--

Betaxolol hydrochloride

Safety Data Sheet

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

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 immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. 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

Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.
------------------------------------	---

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	: 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.

Betaxolol hydrochloride

Safety Data Sheet

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

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

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	: almost white. white.
Appearance	: Crystalline powder.
Molecular mass	: 343.9 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 114 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable

Betaxolol hydrochloride

Safety Data Sheet

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

Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4.5 – 6.5 (20 g/l)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: > 1000 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 3.27 – 3.5
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

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)

Betaxolol hydrochloride (63659-19-8)

LD50 oral rat	998 mg/kg (RTECS NoUA9823000)
---------------	-------------------------------

Skin corrosion/irritation	: Not classified (Lack of data) pH: 4.5 – 6.5 (20 g/l)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 4.5 – 6.5 (20 g/l)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)

Betaxolol hydrochloride

Safety Data Sheet

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

Reproductive toxicity	: Suspected of damaging the unborn child. May cause harm to breast-fed children.
STOT-single exposure	: Not classified (Lack of data)
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 (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

Betaxolol hydrochloride (63659-19-8)

LC50 - Fish [1]	> 100 mg/l (96 Hours, Danio rerio(zebra fish) <tx:_OECD_236>
EC50 - Crustacea [1]	35.2 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method)
ErC50 algae	15.3 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)

12.2. Persistence and degradability

Betaxolol hydrochloride (63659-19-8)

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

12.3. Bioaccumulative potential

Betaxolol hydrochloride (63659-19-8)

Partition coefficient n-octanol/water (Log Pow)	3.27 – 3.5
---	------------

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

Betaxolol hydrochloride

Safety Data Sheet

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

ADR	IMDG	IATA
14.1. UN number or ID number		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards		
Not applicable	Not applicable	Not applicable
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

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 (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 (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)

Betaxolol hydrochloride

Safety Data Sheet

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

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.1	Synonyms	Removed
1.1	Name	Modified
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified
2.3	Other information	Added
2.3	Other hazards which do not result in classification	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after eye contact	Added
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	General measures	Added
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.2	Environmental precautions	Added

Betaxolol hydrochloride

Safety Data Sheet

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

Indication of changes		
Section	Changed item	Comments
6.3	For containment	Added
6.3	Methods for cleaning up	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Added
7.1	Precautions for safe handling	Added
7.1	Hygiene measures	Added
7.2	Packaging materials	Added
7.2	Storage conditions	Added
7.3	Specific end uses	Removed
8.2	Eye protection	Added
8.2	Respiratory protection	Added
8.2	Hand protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Molecular mass	Added
9	Colour	Added
9	Appearance	Modified
9	pH	Added
9	Melting point	Added
9	Solubility in water	Added
9	Partition coefficient n-octanol/water (Log Pow)	Added
10.1	Reactivity	Removed
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	ATE CLP (oral)	Modified
11.1	LD50 oral rat	Modified
12.1	Ecology - general	Removed
12.1	ErC50 algae	Added
12.1	LC50 - Fish [1]	Added
12.1	EC50 - Crustacea [1]	Added

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H319	Causes serious eye irritation.

Betaxolol hydrochloride

Safety Data Sheet

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

Full text of H- and EUH-statements:	
H361d	Suspected of damaging the unborn child.
H362	May cause harm to breast-fed children.
H412	Harmful to aquatic life with long lasting effects.
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 2	Reproductive toxicity, Category 2

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. 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.