

Nebivolol impurity B

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 04/08/2025 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 : Nebivolol impurity B
Chemical name : (1RS,1'RS)-2,2'-azanediylbis[1-[(2SR)-6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl]ethan-1-ol] hydrochloride
Product code : 202100174

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
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) (oral).

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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 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

Other information : 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]
(1RS,1'RS)-2,2'-azanediylbis[1-[(2SR)-6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl]ethan-1-ol] hydrochloride	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 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

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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

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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	: Not available
Molecular mass	: 441.9 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 201 – 204 °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	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
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

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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)

(1RS,1'RS)-2,2'-azanediylobis[1-[(2SR)-6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl]ethan-1-ol] hydrochloride

LD50 oral rat	> 300 – < 2000 mg/kg (estimated value)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
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 (Inconclusive data)
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Causes damage to organs (cardiovascular system) (oral).
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)

12.2. Persistence and degradability

(1RS,1'RS)-2,2'-azanediylobis[1-[(2SR)-6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl]ethan-1-ol] hydrochloride

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
14.1. UN number or ID number		
Not regulated for transport		
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
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

Air transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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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
	ERG code (IATA)	Removed
	Special provisions (IATA)	Removed
	CAO max net quantity (IATA)	Removed
	CAO packing instructions (IATA)	Removed
	PCA max net quantity (IATA)	Removed
	PCA packing instructions (IATA)	Removed
	PCA limited quantity max net quantity (IATA)	Removed
	PCA Limited quantities (IATA)	Removed
	PCA Excepted quantities (IATA)	Removed
	Danger labels (IATA)	Removed
	Proper Shipping Name (IATA)	Removed
	Proper Shipping Name (IMDG)	Removed
	Danger labels (IMDG)	Removed
	EmS-No. (Spillage)	Removed
	EmS-No. (Fire)	Removed
	Limited quantities (IMDG)	Removed
	Stowage and handling (IMDG)	Removed

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Indication of changes		
Section	Changed item	Comments
	Stowage category (IMDG)	Removed
	Tank special provisions (IMDG)	Removed
	Tank instructions (IMDG)	Removed
	IBC special provisions (IMDG)	Removed
	IBC packing instructions (IMDG)	Removed
	Excepted quantities (IMDG)	Removed
	Special provisions (IMDG)	Removed
	Special provisions for carriage - Loading, unloading and handling (ADR)	Removed
	Special provisions for carriage - Bulk (ADR)	Removed
	Special provisions for carriage - Packages (ADR)	Removed
	Tank code (ADR)	Removed
	Portable tank and bulk container special provisions (ADR)	Removed
	Portable tank and bulk container instructions (ADR)	Removed
	Mixed packing provisions (ADR)	Removed
	Special packing provisions (ADR)	Removed
	Packing instructions (ADR)	Removed
	Vehicle for tank carriage	Removed
	Supersedes version of	Added
	Revision date	Added
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	Signal word (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures after skin contact	Modified

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Indication of changes		
Section	Changed item	Comments
4.1	First-aid measures after eye contact	Modified
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
6.3	Methods for cleaning up	Added
6.3	For containment	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Precautions for safe handling	Added
7.1	Hygiene measures	Added
7.1	Additional hazards when processed	Added
7.2	Storage conditions	Added
7.2	Packaging materials	Added
7.3	Specific end uses	Removed
8.2	Respiratory protection	Added
8.2	Eye 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	Melting point	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	LD50 oral rat	Added
11.1	ATE CLP (dust,mist)	Removed
11.1	ATE CLP (vapours)	Removed
11.1	ATE CLP (gases)	Removed
11.1	ATE CLP (dermal)	Removed
12.1	Ecology - general	Removed

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Indication of changes		
Section	Changed item	Comments
14.1	UN-No. (ADR)	Removed
14.1	UN-No. (IMDG)	Removed
14.1	UN-No. (IATA)	Removed
14.2	Proper Shipping Name (ADR)	Removed
14.3	Danger labels (ADR)	Removed
14.3	Class (ADR)	Removed
14.4	Packing group (IATA)	Removed
14.4	Packing group (IMDG)	Removed
14.4	Packing group (ADR)	Removed
14.6	Special packing provisions (IMDG)	Removed
14.6	Packing instructions (IMDG)	Removed
14.6	Transport category (ADR)	Removed
14.6	Special provisions (ADR)	Removed
14.6	Excepted quantities (ADR)	Removed
14.6	Limited quantities (ADR)	Removed
14.6	Tunnel restriction code (ADR)	Removed
14.6	Hazard identification number (Kemler No.)	Removed
14.6	Classification code (ADR)	Removed

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) (oral).
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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