

Nebivolol impurity B

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 03/04/2023 Dáta athbheithnithe: 04/08/2025 Supersedes version of: 03/04/2023 Leagan: 2.0

CUID 1: Sainaitheant na substainte / an mheascáin agus na cuideachta / an ghnóthais

1.1. Sainaitheantóir táirge

Foirm an táirge	: 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
Cód an táirge	: 202100174

1.2. Úsáidí ábhartha sainaitheanta na substainte nó an mheascáin agus úsáidí atá dímholta

Úsáidí sainaitheanta ábhartha

Úsáid na substainte / an mheascáin	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

Úsáidí dímholta

Restrictions on use	: Not for food, drug or home use
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1.3. Sonraí um sholáthraí na bileoige sonraí sábháilteachta

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EDQM, Council of Europe
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F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
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1.4. Uimhir ghutháin éigeandála

Uimhir éigeandála	: +33(0)390215608
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CUID 2: Aithint guaiseacha

2.1. Aicmiú na substainte nó an mheascáin

Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]

Géarthocsaineacht (bhéil), Catagóir 4	H302
Tocsaineacht atáirgeach, Catagóir 2	H361
Tocsaineacht sain-spriocorgáin – aon nochtadh amháin, Catagóir 1	H370

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

Éifeachtaí díobhálacha fisiceimiceacha, um shláinte an duine agus um an comhshaoil

Díobhálach má shlogtar. Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. Déanann sé damáiste d'orgáin.

2.2. Eilimintí lipéid

Lipéadú de réir Rialachán (CE) Uimh. 1272/2008 [CLP]

Hazard pictograms (CLP)	:		
		GHS07	GHS08

Signal word (CLP)	: Contúirt
Hazard statements (CLP)	: H302 - Díobhálach má shlogtar. H361 - Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa

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Ráitis réamhchúraim (CLP)

- bhroinn.
- H370 - Déanann sé damáiste d'orgáin (cardiovascular system) (bhéal).
- : P201 - Faigh treoracha speisialta roimh úsáid.
- P202 - Ná lámhsigh go dtí go léifear agus go dtuigfear gach ráiteas réamhchúraim sábháilteachta.
- P260 - Ná hanálaigh deannach/múch/gás/ceo/gala/sprae.
- P264 - Nigh ... go lánchúramach tar éis lámhsithe.
- P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid.
- P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe.
- P301+P312 - MÁ SHLOGTAR: Cuir glao ar ar dhochtúir má bhraitheann tú tinn.
- P308+P311 - I gCÁS nochtá nó má mheastar a bheith nochtaithe: Cuir glao ar IONAD NIMHE nó ar dhochtúir.
- P308+P313 - I gCÁS nochtá nó má mheastar a bheith nochtaithe: Faigh comhairle/cúram liachta.
- P321 - Cóir liachta ar leith (féach threoir gharchabhrach forlíontach ar an lipéad seo).
- P330 - Sruthlaítear an béal.
- P405 - Stóráil faoi ghlas.
- P501 - Diúscair an t-ábhar/an coimeádán i ...

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

Hazard pictograms (CLP)



GHS08

2.3. Guaiseacha eile

Faisnéis eile

- : Warning - substance not yet tested completely.

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

Ainm	Sainaitheantóir táirge		Aicme de réir Rialachán (CE) Uimh. 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 (Bhéil), H302 (ATE=500 mg/kg méachan coirp) Repr. 2, H361 STOT SE 1, H370

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

CUID 4: Bearta garchabhrach

4.1. Cur síos ar na bearta garchabhrach

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- Bearta garchabhrach tar éis ionanáilaithe : Tabhair an duine amach faoin aer úr agus coinnigh é i riocht ina bhféadfadh sé anáil a tharraingt go réidh. Allow the victim to rest. If the person feels unwell : Faigh comhairle/cúram liachta.
- Bearta garchabhrach tar éis teagmhála leis an gcráiceann : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- Bearta garchabhrach tar éis teagmhála leis an tsúil : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- Bearta garchabhrach tar éis iontógála : Rinse mouth out with water (only if the person is conscious). Ná tabhair aon rud ó bhéal do dhuine atá gan aithne. Cuir glao láithreach ar IONAD NIMHE/ar dhochtúir.

4.2. Na siomptóim agus na héifeachtaí is tábhachtaí, idir shiomptóim ghéarmhíochaine agus shiomptóim mhoillithe

Níl aon fhaisnéis bhreise ar fáil

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4.3. Léiriú ar aon chóir leighis láithreach agus aon chóir speisialta atá ag teastáil

Níl aon fhaisnéis bhreise ar fáil

CUID 5: Bearta comhrac dóiteáin

5.1. Meáin múchta

- Meáin oiriúnacha um múchadh : Use extinguishing media appropriate for surrounding fire. Dé-ocsaíd charbóin. Water spray. Dry powder. Extinguishing blanket.
- Meáin mhí-oiriúnacha um múchadh : Do not use a heavy water stream.

5.2. Guaiseacha speisialta a eascraíonn as an tsubstaint nó as an meascán

- 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. Comhairle do chomhraiceoirí dóiteáin

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Cosaint i rith comhrac dóiteáin : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

CUID 6: Bearta i gcás scaoileadh de thaisme

6.1. Réamhchúiraimí pearsanta, trealamh cosanta agus nósanna imeachta éigeandála

- Bearta ginearálta : Avoid contact with skin, eyes and clothing.
- Do phearsanra neamh-éigeandála**
- Emergency procedures : Evacuate unnecessary personnel.
- D'fhreagróirí éigeandála**
- 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. Réamhchúiraimí comhshaoil

Ná scaoiltear amach sa chomhshaoil. Prevent entry to sewers and public waters.

6.3. Modhanna agus ábhar maidir le coimeád agus glanadh suas

- I gcomhair srianta : Absorb with an inert material and place in an appropriate waste disposal container.
- Modhanna um ghlanadh : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Tagairt do chodanna eile

See Section 13 for disposal information.

CUID 7: Láimhseáil agus stóráil

7.1. Réamhchúiraimí maidir le láimhseáil shábháilte

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Réamhchúiraimí maidir le láimhseáil shábháilte : Seachain gach nochtadh gan ghá. Ensure good ventilation of the work station.
- Bearta sláinteachais : Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid. Níor chóir éadaí éillithe oibre a ligean amach as an láthair oibre. Wash hands before work breaks and after finishing work.

7.2. Coinníollacha stórála sábháilte, lena n-áirítear aon neamhlú

- Coinníollacha stórála : Stóráil in áit dhea-aeráilte. Coimeád an coimeádán dúnta go docht. Keep away from heat and direct sunlight.
- Packaging materials : Keep in original containers.

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7.3. Úsáid shonrach deiridh nó úsáid sonracha deiridh

Níl aon fhaisnéis bhreise ar fáil

CUID 8: Rialuithe nochtá / cosaint phearsanta

8.1. Paraiméadair rialaithe

Níl aon fhaisnéis bhreise ar fáil

8.2. Rialuithe nochtá

Appropriate engineering controls

Rialuithe iomchuí innealtóireachta:

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

Cosaint súl:

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

Skin protection

Cosaint chraicinn agus choirp:

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

Cosaint lámha:

Caith lámhainní oiriúnacha. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Cosaint riospráide:

In case of dust formation use respirator with filter: P3

CUID 9: Airíonna fisiceacha agus ceimiceacha

9.1. Faisnéis bunaithe ar bhunairíonna fisiceacha agus ceimiceacha

Staid fhisiceach	: Solid
Dath	: Not available
Molecular mass	: 441.9 g/mol
Boladh	: Not available
Tairseach bolaidh	: Not available
Leáphointe	: 201 – 204 °C
Reophointe	: Not available
Fiuchphointe	: Not available
Inadhainteacht	: Not available
Lower explosion limit	: Ní bhaineann le hábhar
Upper explosion limit	: Ní bhaineann le hábhar
Splancphointe	: Ní bhaineann le hábhar
Teocht uath-adhainte	: Ní bhaineann le hábhar
Teocht dianscaoilte	: Not available
pH	: Not available
pH solution	: Not available
Slaodacht, cinéimiteach	: Ní bhaineann le hábhar
Intuaslagthacht	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Galbhrú	: Not available
Vapour pressure at 50°C	: Not available
Dlús	: Not available
Dlús coibhneasta	: Not available
Galdlús coibhneasta ag 20°C	: Ní bhaineann le hábhar
Particle size	: Not available

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9.2. Faisnéis eile

Níl aon fhaisnéis bhreise ar fáil

CUID 10: Cobhsaíocht agus imoibríocht

10.1. Imoibríocht

Níl aon fhaisnéis bhreise ar fáil

10.2. Cobhsaíocht cheimiceach

Níl aon fhaisnéis bhreise ar fáil

10.3. D'fhéadfadh a bheith ina chúis le fhrithghníomhartha guaiseacha

Níl aon fhaisnéis bhreise ar fáil

10.4. Coinníollacha lena seachaint

Níl aon fhaisnéis bhreise ar fáil

10.5. Ábhair neamh-chomhoiriúnacha

Níl aon fhaisnéis bhreise ar fáil

10.6. Táirgí dianscailte guaiseacha

Níl aon fhaisnéis bhreise ar fáil

CUID 11: Faisnéis thocsaineolaíoch

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

Acute toxicity (oral) : Díobhálach má shlogtar.
Acute toxicity (dermal) : ()
Acute toxicity (inhalation) : ()

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

LD50 ó bhéal francach	> 300 – < 2000 mg/kg (estimated value)
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Creimeadh/greannú craicinn : ()
Damáiste/greannú tromchúiseach súl : ()
Íogru riospráide nó craicinn : ()
Só-ghineacht ghaiméite : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Carcanaigineacht : ()
Tocsaineacht atáirgthe : Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) : Déanann sé damáiste d'orgáin (cardiovascular system) (bhéal).
Tocsaineacht sain-spriocorgáin (ilnochtadh) : ()
Guais asúite : ()

11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

CUID 12: Faisnéis éiceolaíochta

12.1. Tocsaineacht

Guaiseach don chomhshaol uisceach, ghearrthéarmach (géarghuais) : ()
Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) : ()

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12.2. Inchoimeádachas agus díghrádaitheacht

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

Inchoimeádachas agus díghrádaitheacht	Not rapidly degradable
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12.3. Acmhainneacht bhithbhailitheach

Níl aon fhaisnéis bhreise ar fáil

12.4. Soghluaisteacht san ithir

Níl aon fhaisnéis bhreise ar fáil

12.5. Torthaí an mheasúnaithe PBT agus vPvB

Níl aon fhaisnéis bhreise ar fáil

12.6. Endocrine disrupting properties

Níl aon fhaisnéis bhreise ar fáil

12.7. Éifeachtaí díobhálacha eile

Níl aon fhaisnéis bhreise ar fáil

CUID 13: Breithnithe diúscartha

13.1. Modhanna cóireála dramhaíola

Níl aon fhaisnéis bhreise ar fáil

CUID 14: Faisnéis Iompair

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Neamhrialaithe		
14.2. Ainm seolta ceart UN		
Not regulated	Not regulated	Not regulated
14.3. Aicme nó aicmí guaise iompair		
Not regulated	Not regulated	Not regulated
14.4. Grúpa pacála		
Not regulated	Not regulated	Not regulated
14.5. Guaiseacha comhshaoil		
Not regulated	Not regulated	Not regulated

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

Not regulated

Iompar ar muir

Not regulated

Aeriompar

Not regulated

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14.7. Maritime transport in bulk according to IMO instruments

Ní bhaineann le hábhar

CUID 15: Faisnéis rialála

15.1. Rialacháin/reachtaíocht sábháilteacht, sláinte agus chomhshaoil a bhaineann go sonrach leis an tsubstaint nó an meascán

Rialacháin de chuid an AE

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. Measúnú sábháilteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

CUID 16: Faisnéis eile

Léiriú ar na hathruithe

Cuid	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

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Léiriú ar na hathruithe		
Cuid	Changed item	Comments
	EmS-No. (Spillage)	Removed
	EmS-No. (Fire)	Removed
	Limited quantities (IMDG)	Removed
	Stowage and handling (IMDG)	Removed
	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 provision (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
	Packing provisions (ADR)	Removed
	Packing instructions (ADR)	Removed
	Vehicle for tank carriage	Removed
	Supersedes version of	Added
	Dáta athbheithnithe	Added
1.1	Ainm	Modified
1.2	Restrictions on use	Modified
1.2	Úsáid na substainte / an mheascáin	Modified
1.2	Príomhchatagóir úsáide	Removed
2.1	Éifeachtaí díobhálacha fisiciceimiceacha, um shláinte an duine agus um an comhshaol	Modified
2.1	Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]	Modified
2.2	Signal word (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Ráitis réamhchúraim (CLP)	Modified
2.3	Faisnéis eile	Added

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Léiriú ar na hathruithe		
Cuid	Changed item	Comments
4.1	First-aid measures general	Added
4.1	Beartha garchabhrach tar éis ionanáilaithe	Added
4.1	Beartha garchabhrach tar éis iontógála	Added
4.1	Beartha garchabhrach tar éis teagmhála leis an gcráiceann	Modified
4.1	Beartha garchabhrach tar éis teagmhála leis an tsúil	Modified
5.1	Meáin mhí-oiriúnacha um múchadh	Added
5.1	Meáin oiriúnacha um múchadh	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Guais dóiteáin	Removed
5.3	Cosaint i rith comhrac dóiteáin	Added
5.3	Firefighting instructions	Modified
6.1	Beartha ginearálta	Added
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.2	Réamhchúraimí comhshaoil	Added
6.3	Modhanna um ghlanadh	Added
6.3	I gcomhair srianta	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Réamhchúraimí maidir le láimhseáil shábháilte	Added
7.1	Beartha sláinteachais	Added
7.1	Additional hazards when processed	Added
7.2	Coinníollacha stórála	Added
7.2	Packaging materials	Added
7.3	Specific end uses	Removed
8.2	Cosaint riospráide	Added
8.2	Cosaint súl	Added
8.2	Cosaint lámha	Modified
8.2	Rialuithe iomchuí innealtóireachta	Modified
8.2	Cosaint chraicinn agus choirp	Modified
9	Molecular mass	Added
9	Leáphointe	Added
10.1	Imoibríocht	Removed
10.3	D'fhéadfadh a bheith ina chúis le fhrithghníomhartha guaiseacha	Removed
10.5	Ábhair neamh-chomhoiriúnacha	Removed
10.6	Táirgí dianscaoilte guaiseacha	Removed

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Léiriú ar na hathruithe		
Cuid	Changed item	Comments
11.1	LD50 ó bhéal francach	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	Éiceolaíocht - ginearálta	Removed
14.1	(ADR) (ADR)	Removed
14.1	(ADR) (IMDG)	Removed
14.1	(ADR) (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	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 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 4
H302	Díobhálach má shlogtar.
H361	Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
H370	Déanann sé damáiste d'orgáin (cardiovascular system) (bhéal).
Repr. 2	Tocsaineacht atáirgeach, Catagóir 2
STOT SE 1	Tocsaineacht sain-spiocorgáin – aon nochtadh amháin, Catagóir 1

Safety Data Sheet (SDS), EU

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