

Isoprenaline impurity A

Bileog Sonraí Sábhálteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 31/01/2023 Leagan: 1.0

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

1.1. Sainaitheantóir táirge

| | |
|-----------------|--|
| Foirm an táirge | : Substance |
| Substance name | : Isoprenaline impurity A |
| Chemical name | : 3',4'-dihydroxy-2-(isopropylamino)-acetophenone hydrochloride |
| Cód an táirge | : 202200390 |
| Synonyms | : Ethanone, 1-(3,4-dihydroxyphenyl)-2-[(1-methylethyl)amino]-, hydrochloride |

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

1.2.1. Úsáidí sainaitheanta ábhartha

| | |
|------------------------------------|--|
| Príomhchatagóir úsáide | : The product is intended for research, analysis and scientific education. |
| Úsáid na substainte / an mheascáin | : For professional use only |
| Function or use category | : Laboratory chemicals |

1.2.2. Úsáidí dímholta

| | |
|---------------------|--|
| Restrictions on use | : Do not use : Ingestion, Inhalation, Dermal |
|---------------------|--|

1.3. Sonraí um sholáthraí na bileoige sonraí sábhálteachta

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. Uimhir ghutháin éigeandála

| | |
|-------------------|-------------------|
| Uimhir éigeandála | : +33(0)390215608 |
|-------------------|-------------------|

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

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

Expert judgement and weight of evidence determination.

2.2. Eilimintí lipéid

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

Hazard pictograms (CLP)



GHS07

| | |
|---------------------------|--|
| Signal word (CLP) | : Rabhadh |
| Hazard statements (CLP) | : H302 - Díobhálach má shlogtar. |
| Ráitis réamhchúraim (CLP) | : P264 - Nigh ... go lánchúramach tar éis láimhsithe. P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid. P301+P312 - MÁ SHLOGTAR: Cuir glao ar IONAD NIMHE nó ar dhoctúir má bhraitheann tú tinn. P330 - Sruthlaítear an béal. P501 - Diúscair an t-ábhar/an coimeádán i ... |

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

Isoprenaline impurity A

Bileog Sonraí Sábhálteachta

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

No labelling required

2.3. Guaiseacha eile

Níl aon fhaisnéis bhreise ar fáil

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

| Ainm | Sainaitheantóir táirge | | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP] |
|---|------------------------|-------|--|
| 3',4'-dihydroxy-2-(isopropylamino)-acetophenone hydrochloride | - | ≤ 100 | Acute Tox. 4 (Bhéil), H302 (ATE=500 mg/kg meáchan coirp) |

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

3.2. Meascán

Ní bhaineann le hábhar

CUID 4: Bearta garchabhrach

4.1. Cur síos ar na bearta garchabhrach

Bearta garchabhrach tar éis teagmhála leis an gcráiceann : Wipe off as much as possible (using a clean, soft, absorbent material).

Bearta garchabhrach tar éis teagmhála leis an tsúil : Rinse eyes with water as a precaution.

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

Níl aon fhaisnéis bhreise ar fáil

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 : Extinguishing blanket.

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

Guais dóiteáin : See Heading 2.2.

5.3. Comhairle do chomhraiceoirí dóiteáin

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

CUID 6: Bearta i gcás scaoileadh de thaisme

6.1. Réamhchúraimí pearsanta, trealamh cosanta agus nósanna imeachta éigeandála

6.1.1. Do phearsanra neamh-éigeandála

Emergency procedures : Seachain gach nochtadh gan ghá.

6.1.2. D'fhreagróirí éigeandála

Níl aon fhaisnéis bhreise ar fáil

Isoprenaline impurity A

Bileog Sonraí Sábhálteachta

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

6.2. Réamhchúraimí comhshaoil

Níl aon fhaisnéis bhreise ar fáil

6.3. Modhanna agus ábhar maidir le coimeád agus glanadh suas

Níl aon fhaisnéis bhreise ar fáil

6.4. Tagairt do chodanna eile

Níl aon fhaisnéis bhreise ar fáil

CUID 7: Láimhseáil agus stóráil

7.1. Réamhchúraimí maidir le láimhseáil shábháilte

Níl aon fhaisnéis bhreise ar fáil

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

Níl aon fhaisnéis bhreise ar fáil

7.3. Úsáid shonrach deiridh nó úsáid sonracha deiridh

See Heading 1.

CUID 8: Rialuithe nochtá / cosaint phearsanta

8.1. Paraiméadair rialaithe

8.1.1 National occupational exposure and biological limit values

Níl aon fhaisnéis bhreise ar fáil

8.1.2. Recommended monitoring procedures

Níl aon fhaisnéis bhreise ar fáil

8.1.3. Air contaminants formed

Níl aon fhaisnéis bhreise ar fáil

8.1.4. DNEL and PNEC

Níl aon fhaisnéis bhreise ar fáil

8.1.5. Control banding

Níl aon fhaisnéis bhreise ar fáil

8.2. Rialuithe nochtá

8.2.1. Appropriate engineering controls

Rialuithe iomchuí innealtóireachta:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Níl aon fhaisnéis bhreise ar fáil

8.2.2.2. Skin protection

Cosaint chraicinn agus choirp:

Lab coat

Cosaint lámha:

Protective gloves

8.2.2.3. Respiratory protection

Níl aon fhaisnéis bhreise ar fáil

Isoprenaline impurity A

Bileog Sonraí Sábháilteachta

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

8.2.2.4. Thermal hazards

Níl aon fhaisnéis bhreise ar fáil

8.2.3. Environmental exposure controls

Níl aon fhaisnéis bhreise ar fáil

CUID 9: Airíonna fisiceacha agus ceimiceacha

9.1. Faisnéis bunaithe ar bhunairíonna fisiceacha agus ceimiceacha

| | |
|---|--------------------------|
| Staid fhisiceach | : Solid |
| Dath | : Not available |
| Boladh | : Not available |
| Tairseach bolaidh | : Not available |
| Leáphointe | : Not available |
| Reophointe | : Not available |
| Fiuchphointe | : Not available |
| Inadhainteacht | : Not available |
| Teorainneacha pléascacha | : Ní bhaineann le hábhar |
| 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 |

9.2. Faisnéis eile

9.2.1. Information with regard to physical hazard classes

Níl aon fhaisnéis bhreise ar fáil

9.2.2. Other safety characteristics

Níl aon fhaisnéis bhreise ar fáil

CUID 10: Cobhsaíocht agus imoibríocht

10.1. Imoibríocht

Stable under normal conditions.

10.2. Cobhsaíocht cheimiceach

Níl aon fhaisnéis bhreise ar fáil

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

None known.

10.4. Coinníollacha lena seachaint

Níl aon fhaisnéis bhreise ar fáil

Isoprenaline impurity A

Bileog Sonraí Sábhálteachta

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

10.5. Ábhair neamh-chomhoiriúnacha

None under normal use. See Section 7.

10.6. Táirgí dianscaoilte guaiseacha

When heated to decomposition, emits dangerous fumes.

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) | : Not classified (Lack of data) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |

3',4'-dihydroxy-2-(isopropylamino)-acetophenone hydrochloride

| | |
|--|---|
| LD50 ó bhéal francach | 300 – 2000 mg/kg |
| Creimeadh/greannú craicinn | : Not classified (Lack of data) |
| Damáiste/greannú tromchúiseach súl | : Not classified (Lack of data) |
| Íogró riospráide nó craicinn | : Not classified (Lack of data) |
| Só-ghineacht ghaiméite | : Not classified (Lack of data) |
| Carcanaigineacht | : Not classified (Lack of data) |
| Tocsaineacht atáirgthe | : Not classified (Lack of data) |
| Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) | : Not classified (Lack of data) |
| Tocsaineacht sain-spriocorgáin (ilnochtadh) | : Not classified (Lack of data) |
| Guais asúite | : Not classified (Technical impossibility to obtain the data) |

11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

CUID 12: Faisnéis éiceolaíochta

12.1. Tocsaineacht

| | |
|---|--|
| Éiceolaíocht - ginearálta | : Presents no specific risk for the environment. |
| Guaiseach don chomhshaol uisceach, ghearrthéarmach (géarghuais) | : Not classified (Lack of data) |
| Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) | : Not classified (Lack of data) |
| Not rapidly degradable | |

12.2. Inchoimeádachas agus díghrádaitheacht

Níl aon fhaisnéis bhreise ar fáil

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

Isoprenaline impurity A

Bileog Sonraí Sábhálteachta

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

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 | | |
| Ní bhaineann le hábhar | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| 14.2. Ainm seolta ceart UN | | |
| Ní bhaineann le hábhar | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| 14.3. Aicme nó aicmí guaise iompair | | |
| Ní bhaineann le hábhar | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| 14.4. Grúpa pacála | | |
| Ní bhaineann le hábhar | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| 14.5. Guaiseacha comhshaoil | | |
| Ní bhaineann le hábhar | Ní bhaineann le hábhar | Ní bhaineann le hábhar |

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

Ní bhaineann le hábhar

Iompar ar muir

Ní bhaineann le hábhar

Aeriompar

Ní bhaineann le hábhar

14.7. Maritime transport in bulk according to IMO instruments

Ní bhaineann le hábhar

CUID 15: Faisnéis rialála

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

15.1.1. 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

Isoprenaline impurity A

Bileog Sonraí Sábháilteachta

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

PIC Regulation (Prior Informed Consent)

Ní bhaineann le hábhar

POP Regulation (Persistent Organic Pollutants)

Ní bhaineann le hábhar

Ozone Regulation (1005/2009)

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

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)

15.1.2. Rialacháin náisiúnta

Níl aon fhaisnéis bhreise ar fáil

15.2. Measúnú sábháilteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

CUID 16: Faisnéis eile

Full text of H- and EUH-statements:

| | |
|----------------------|---------------------------------------|
| Acute Tox. 4 (Bhéil) | Géarthocsaineacht (bhéil), Catagóir 4 |
| H302 | Díobhálach má shlogtar. |

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. 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 article.