

(1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1-amine;(2S)-2-hydroxy-2-phenylacetic acid

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 03/04/2023 Leagan: 1.0

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

1.1. Sainaitheantóir táirge

Foirm an táirge : Substance
Substance name : (1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1-amine;(2S)-2-hydroxy-2-phenylacetic acid
Cód an táirge : 202000100

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 sábháilteachta

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
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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 3 H301
Íogru craicinn, Catagóir 1 H317
Tocsaineacht sain-spricorgáin – Athnochtadh, Catagóir 2 H373
Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 2 H411
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) :



GHS06

GHS08

GHS09

Signal word (CLP) :

Contúirt

Hazard statements (CLP) :

H301 - Tocsaineach má shlogtar.

H317 - D'fhéadfadh sé a bheith ina chúis le frithghníomh ailléirgeach craicinn.

H373 - D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh.

H411 - Tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.

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Ráitis réamhchúraim (CLP)

- : P260 - Ná hanálaigh deannach/múch/gás/ceo/gala/sprae.
- P264 - Nigh ... go lánchúramach tar éis láimhsithe.
- P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid.
- P272 - Níor chóir éadaí éillithe oibre a ligean amach as an láthair oibre.
- P273 - Ná scaoiltear amach sa chomhshaoil.
- P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe.
- P301+P310 - MÁ SHLOGTAR: Cuir glao láithreach ar IONAD NIMHE nó ar dhoctúir.
- P302+P352 - I gCÁS TEAGMHÁLA LEIS AN gCRAICEANN: Nigh le neart uisce.
- P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn.
- P321 - Cóir liachta ar leith (féach threoir gharchabhrach forlíontach ar an lipéad seo).
- P330 - Sruthlaítear an béal.
- P333+P313 - Má tharlaíonn greannú nó gríos craicinn: Faigh comhairle/cúram liachta.
- P362+P364 - Bain díot aon éadaí éillithe agus nigh iad roimh iad a athúsáid.
- P391 - Bailigh doirteadh.
- 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)



GHS06

GHS08

2.3. Guaiseacha eile

Níl aon fhaisnéis bhreise ar fáil

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

| Ainm | Sainitheantóir táirge | | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP] |
|--------------------------------------------------------------------------------------|-----------------------|-------|------------------------------------------------------------------------------------------------------------------------------|
| (1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1-amine;(2S)-2-hydroxy-2-phenylacetic acid | - | ≤ 100 | Acute Tox. 3 (Bhéil), H301 (ATE=100 mg/kg meáchan coirp) Skin Sens. 1, H317 STOT RE 2, H373 Aquatic Chronic 2, H411 |

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 ionanáilaithe : Move to fresh air. Allow affected person to breathe fresh air.
- Bearta garchabhrach tar éis teagmhála leis an gcráiceann : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
- Bearta garchabhrach tar éis teagmhála leis an tsúil : Rinse with water while holding the eyes wide open.
- Bearta garchabhrach tar éis iontógála : Sruthlaítear an béal. Cuir glao láithreach ar IONAD NIMHE/ar dhoctúir. Prolonged medical observation may be indicated.

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

- Symptoms/effects : Delayed adverse effects possible.

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

| | |
|----------------------------------------------------------|--------------------------------|
| Siomptóim/gortuithe tar éis ionanáilaithe | : Insufficient data available. |
| Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann | : Insufficient data available. |
| Siomptóim/gortuithe tar éis teagmhála leis an tsúil | : Insufficient data available. |

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

Faigh comhairle/cúram liachta. If possible show this sheet, if not available show packaging or label.

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

Bearta ginearálta : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.1. Do phearsanra neamh-éigeandála

Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

6.1.2. D'fhreagróirí éigeandála

Níl aon fhaisnéis bhreise ar fáil

6.2. Réamhchúraimí comhshaoil

Níl aon fhaisnéis bhreise ar fáil

6.3. Modhanna agus ábhar maidir le coimeád agus glanadh suas

Modhanna um ghlanadh : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

6.4. Tagairt do chodanna eile

Níl aon fhaisnéis bhreise ar fáil

CUID 7: Láimhseáil agus stóráil

7.1. Réamhchúraimí maidir le láimhseáil shábháilte

Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.

Réamhchúraimí maidir le láimhseáil shábháilte : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.

Bearta sláinteachais : Handle in accordance with good industrial hygiene and safety procedures.

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

Technical measures : Comply with applicable regulations.

Coinníollacha stórála : Stóráil faoi ghlas.

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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. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Cosaint súl:

Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Cosaint chraicinn agus choirp:

Use chemically protective clothing. DIN EN 13034

Cosaint lámha:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

Cosaint riospráide:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

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 | : Ní bhaineann le hábhar. |
| Tairseach bolaidh | : Not available |

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| | |
|-------------------------------------------------|--------------------------|
| 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 dian scaoilte | : 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

Níl aon fhaisnéis bhreise ar fáil

10.4. Coinníollacha lena seachaint

Níl aon fhaisnéis bhreise ar fáil

10.5. Ábhair neamh-chomhoiriúnacha

None under normal use. See Section 7.

10.6. Táirgí dian scaoilte 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) | : Tocsaineach má shlogtar. |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

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| | |
|------------------------------------------------------|--------------------------------------------------------------------------------|
| Creimeadh/greannú craicinn | : Not classified |
| Damáiste/greannú tromchúiseach súl | : Not classified |
| Íoghrú riospráide nó craicinn | : D'fhéadfadh sé a bheith ina chúis le frithghníomh ailléirgeach craicinn. |
| Só-ghineacht ghaiméite | : Not classified |
| Carcanaigineacht | : Not classified |
| Tocsaineacht atáirgthe | : Not classified |
| Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) | : Not classified |
| Tocsaineacht sain-spriocorgáin (ilnochtadh) | : D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| Guais asúite | : Not classified |

11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

CUID 12: Faisnéis éiceolaíochta

12.1. Tocsaineacht

| | |
|-------------------------------------------------------------------|------------------------------------------------------------------|
| Éiceolaíocht - ginearálta | : Hazardous waste. Use suitable disposal containers. |
| Guaiseach don chomhshaol uisceach, ghearrthéarmach (géarghuais) | : Not classified |
| Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) | : Tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |

12.2. Inchoimeádachas agus díghráiditheacht

Níl aon fhaisnéis bhreise ar fáil

12.3. Acmhainneacht bhithbhailitheach

Níl aon fhaisnéis bhreise ar fáil

12.4. Soghluasteacht 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

| | |
|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Regional legislation (waste) | : Dispose in a safe manner in accordance with local/national regulations. |
| Product/Packaging disposal recommendations | : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point. |




CUID 14: Faisnéis Iompair

In accordance with ADR / IMDG / IATA

(1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1-amine;(2S)-2-hydroxy-2-phenylacetic acid

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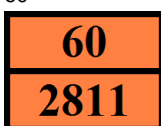
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| ADR | IMDG | IATA |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 14.1. UN number or ID number | | |
| UN 2811 | UN 2811 | UN 2811 |
| 14.2. Ainm seolta ceart UN | | |
| TOXIC SOLID, ORGANIC, N.O.S. | TOXIC SOLID, ORGANIC, N.O.S. | Toxic solid, organic, n.o.s. |
| Transport document description | | |
| UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E), ENVIRONMENTALLY HAZARDOUS | UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS | UN 2811 Toxic solid, organic, n.o.s., 6.1, III, ENVIRONMENTALLY HAZARDOUS |
| 14.3. Aicme nó aicmí guaise iompair | | |
| 6.1 | 6.1 | 6.1 |
|  |  |  |
| 14.4. Grúpa pacála | | |
| III | III | III |
| 14.5. Guaiseacha comhshaoil | | |
| Contúirteach don chomhshaoil: Tá | Contúirteach don chomhshaoil: Tá Truailleán mara: Tá | Contúirteach don chomhshaoil: Tá |

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

| | |
|-------------------------------------------------------------------------|---------------------------|
| Classification code (ADR) | : T2 |
| Special provisions (ADR) | : 274, 614 |
| Limited quantities (ADR) | : 5kg |
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P002, IBC08, LP02, R001 |
| Packing provisions (ADR) | : B3 |
| Mixed packing provisions (ADR) | : MP10 |
| Portable tank and bulk container instructions (ADR) | : T1 |
| Portable tank and bulk container special provisions (ADR) | : TP33 |
| Tank code (ADR) | : SGAH, L4BH |
| Tank special provisions (ADR) | : TU15, TE19 |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 2 |
| Special provisions for carriage - Bulk (ADR) | : VC1, VC2, AP7 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13, CV28 |
| Special provisions for carriage - Operation (ADR) | : S9 |
| Hazard identification number (Kemler No.) | : 60 |
| Orange plates | : |



Tunnel restriction code (ADR) : E

Iompar ar muir

Special provision (IMDG) : 223, 274

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| | |
|------------------------------------|---------------------------------------------------------|
| Packing instructions (IMDG) | : P002 |
| IBC packing instructions (IMDG) | : IBC08 |
| IBC special provisions (IMDG) | : B3 |
| Tank instructions (IMDG) | : T1 |
| Tank special provisions (IMDG) | : TP33 |
| EmS-No. (Fire) | : F-A |
| EmS-No. (Spillage) | : S-A |
| Stowage category (IMDG) | : A |
| Properties and observations (IMDG) | : Toxic if swallowed, by skin contact or by inhalation. |

Aeriompar

| | |
|----------------------------------------------|----------|
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y645 |
| PCA limited quantity max net quantity (IATA) | : 10kg |
| PCA packing instructions (IATA) | : 670 |
| PCA max net quantity (IATA) | : 100kg |
| CAO packing instructions (IATA) | : 677 |
| CAO max net quantity (IATA) | : 200kg |
| Special provisions (IATA) | : A3, A5 |
| ERG code (IATA) | : 6L |

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

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

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

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CUID 16: Faisnéis eile

| Full text of H- and EUH-statements: | |
|-------------------------------------|------------------------------------------------------------------------------|
| Acute Tox. 3 (Bhéil) | Géarthocsaineacht (bhéil), Catagóir 3 |
| Aquatic Chronic 2 | Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 2 |
| H301 | Tocsaineach má shlogtar. |
| H317 | D'fhéadfadh sé a bheith ina chúis le frithghníomh ailléirgeach craicinn. |
| H373 | D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| H411 | Tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |
| Skin Sens. 1 | Íogró craicinn, Catagóir 1 |
| STOT RE 2 | Tocsaineacht sain-spriocorgáin – Athnochtadh, Catagóir 2 |

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.