

Azelastine impurity B

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 24/09/2025 Leagan: 1.0

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

1.1. Sainaitheantóir táirge

| | |
|-----------------|---|
| Foirm an táirge | : Substance |
| Substance name | : Azelastine impurity B |
| Chemical name | : N'-[(4RS)-1-Methylhexahydro-1H-azepin-4-yl]benzohydrazide hydrochloride |
| Uimh. CAS | : 117078-69-0 |
| Cód an táirge | : 202500596 |

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 |
|---------------------|----------------------------------|

1.3. Sonraí um sholáthraí na bileoige sonraí sábháilteachta

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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 4 H302
Full text of H- and EUH-statements: see section 16

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

Díobhálach má shlogtar.

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 réamhchúiraim (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. |

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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.

No labelling required

2.3. Guaiseacha eile

Faisnéis eile : Warning - substance not yet tested completely.

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

| Ainm | Sainitheantóir táirge | | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP] |
|---|------------------------|-------|---|
| N'-[(4RS)-1-Methylhexahydro-1H-azepin-4-yl]benzohydrazide hydrochloride | Uimh. CAS: 117078-69-0 | ≤ 100 | Acute Tox. 4 (Bhéil), H302 (ATE=1690 mg/kg méachan coirp) |

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 dhoctúir. |

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 | : 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. |

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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

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.

7.3. Úsáid shonrach deiridh nó úsáid sonracha deiridh

Níl aon fhaisnéis bhreise ar fáil

CUID 8: Rialuithe nochta / cosaint phearsanta

8.1. Paraiméadair rialaithe

Níl aon fhaisnéis bhreise ar fáil

8.2. Rialuithe nochta

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)

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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 | : 283.8 g/mol |
| Boladh | : Not available |
| Tairseach bolaidh | : Not available |
| Leáphointe | : 180 – 184 °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 | : 5 (25°C, 10 g/L) |
| pH solution | : Not available |
| Slaodacht, cinéimiteach | : Ní bhaineann le hábhar |
| Intuaslagthacht | : Uisce: > 100 g/l |
| 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

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

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10.5. Ábhair neamh-chomhoiriúnacha

Níl aon fhaisnéis bhreise ar fáil

10.6. Táirgí dianscaoilte 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) : ()

N'-[(4RS)-1-Methylhexahydro-1H-azepin-4-yl]benzohydrazide hydrochloride (117078-69-0)

| | |
|-----------------------|------------|
| LD50 ó bhéal francach | 1690 mg/kg |
|-----------------------|------------|

Creimeadh/greannú craicinn : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
pH: 5 (25°C, 10 g/L)

Damáiste/greannú tromchúiseach súl : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
pH: 5 (25°C, 10 g/L)

Íogru riospráide nó craicinn : ()

Só-ghineacht ghaiméite : Not classified

Carcanaigineacht : ()

Tocsaineacht atáirgthe : ()

Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) : ()

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) : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)

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

12.2. Inchoimeádachas agus díghrádaitheacht

N'-[(4RS)-1-Methylhexahydro-1H-azepin-4-yl]benzohydrazide hydrochloride (117078-69-0)

| | |
|---------------------------------------|------------------------|
| Inchoimeádachas agus díghrádaitheacht | Not rapidly degradable |
|---------------------------------------|------------------------|

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

Azelaistine impurity B

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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 dramhaiola

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 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)

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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

Full text of H- and EUH-statements:

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

Safety Data Sheet (SDS), EU

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