

Levodropropizine impurity B

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 01/01/2025 Dáta athbheithnithe: 03/06/2025 Supersedes version of: 01/01/2025 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 | : Levodropropizine impurity B |
| Chemical name | : 1-Phenylpiperazine |
| Uimh. CE | : 202-165-6 |
| Uimh. CAS | : 92-54-6 |
| Cód an táirge | : 202400621 |

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

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 3 | H301 |
| Géarthocsaineacht (dheirmeach), Catagóir 2 | H310 |
| Creimeadh/greannú craicinn, Catagóir 1B | H314 |
| Damáiste tromchúiseach don tsúil/greannú súl, Catagóir 1 | H318 |

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

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

Tocsaineach má shlogtar. Marfach i dteagmháil leis an ggraiceann. Ina chúis le dónna tromchúiseacha craicinn agus le damáiste don tsúil.

2.2. Eilimintí lipéid

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

| | | | |
|-------------------------|---|---|---|
| Hazard pictograms (CLP) | : |  |  |
| | | GHS05 | GHS06 |
| Signal word (CLP) | : | Contúirt | |

Levodropropizine impurity B

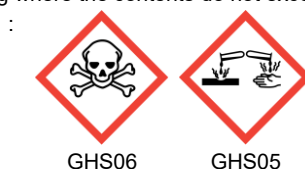
Bileog Sonraí Sábháilteachta

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

| | |
|---------------------------|---|
| Hazard statements (CLP) | : H301 - Tocsaineach má shlogtar. H310 - Marfach i dteagmháil leis an gcráiceann. H314 - Ina chúis le dónna tromchúiseacha craicinn agus le damáiste don tsúil. |
| 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. P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe. P301+P310 - MÁ SHLOGTAR: Cuir glao láithreach ar IONAD NIMHE nó ar dhochtúir. P301+P330+P331 - MÁ SHLOGTAR: Sruthlaítear an béal. NÁ spreagtar urlacan. P302+P352 - I gCÁS TEAGMHÁLA LEIS AN gCRAICEANN: Nigh le neart uisce. P304+P340 - MÁ IONANÁILTEAR: Tabhair an duine amach faoin aer úr agus coinnigh é compordach. P305+P351+P338 - I gCÁS TEAGMHÁLA LEIS NA SÚILE: Sruthlaítear go cúramach le huisce ar feadh roinnt nóiméad. Tóg amach na tadhall-lionsaí, más ann dóibh agus más furasta é sin a dhéanamh. Lean den sruthlú. P310 - Cuir glao láithreach ar IONAD NIMHE nó ar dhochtúir. P321 - Cóir liachta ar leith (féach threoir gharchabhrach forlíontach ar an lipéad seo). P330 - Sruthlaítear an béal. P361+P364 - Bain díot láithreach na héadaí éillithe go léir agus nigh iad roimh iad a athúsáid. 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)



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] |
|--------------------|---|-------|---|
| 1-Phenylpiperazine | Uimh. CAS: 92-54-6 Uimh. CE: 202-165-6 | ≤ 100 | Acute Tox. 3 (Bhéil), H301 (ATE=210 mg/kg meáchan coirp) Acute Tox. 2 (Deirmeach), H310 (ATE=149 mg/kg meáchan coirp) Skin Corr. 1B, H314 Eye Dam. 1, H318 |

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. Obtain medical attention if breathing difficulty persists. |
| Bearta garchabhrach tar éis teagmhála leis an gcráiceann | : Bain díot láithreach na héadaí éillithe go léir. Rinse immediately and plentifully with water and take medical advice. |
| Bearta garchabhrach tar éis teagmhála leis an tsúil | : Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Tóg amach na tadhall-lionsaí, más ann dóibh agus más furasta é sin a dhéanamh. Lean den sruthlú. Consult an eye specialist immediately. |

Levodropropizine impurity B

Bileog Sonraí Sábhálteachta

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

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

Siomptóim/gortuithe tar éis ionanáilthe : May cause shortness of breath, tightness of the chest, a sore throat and cough.
Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann : Marfach i dteagmháil leis an gcráiceann. Causes severe burns.
Siomptóim/gortuithe tar éis teagmhála leis an tsúil : Ina chúis le damáiste tromchúiseach don tsúil. Redness, pain.
Siomptóim/gortuithe tar éis iontógála : Burns to the gastric/intestinal mucosa.

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. Réamhchúraimí pearsanta, trealamh cosanta agus nósanna imeachta éigeandála

Bearta ginearálta : Avoid contact with skin, eyes and clothing.

Do phearsana 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. Réamhchúraimí 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. Réamhchúraimí maidir le láimhseáil shábháilte

Réamhchúraimí maidir le láimhseáil shábháilte : Seachain gach nochtadh gan ghá. Ensure good ventilation of the work station.

Levodropropizine impurity B

Bileog Sonraí Sábhálteachta

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

Bearta sláinteachais : Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid. Níor chóir éadaí éillithe oibre a lígean amach as an láthair oibre. Wash hands before work breaks and after finishing work.

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

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

UID 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 mist, spray or aerosol exposure: Breathing apparatus with filter (P3). Where excessive vapour may result, wear approved mask .

UID 9: Airíonna fisiceacha agus ceimiceacha

9.1. Faisnéis bunaithe ar bhunairíonna fisiceacha agus ceimiceacha

| | |
|-------------------------|-----------------|
| Staid fhisiceach | : Leachtach |
| Dath | : Not available |
| Molecular mass | : 163.2 g/mol |
| Boladh | : Not available |
| Tairseach bolaidh | : Not available |
| Leáphointe | : ≈ 18 °C |
| Reophointe | : Not available |
| Fiuchphointe | : Not available |
| Inadhainteacht | : Not available |
| Lower explosion limit | : Not available |
| Upper explosion limit | : Not available |
| Splancphointe | : 140 °C |
| Teocht uath-adhainte | : Not available |
| Teocht dianscaoilte | : Not available |
| pH | : Not available |
| Slaodacht, cinéimiteach | : Not available |

Levodropropizine impurity B

Bileog Sonraí Sábháilteachta

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

| | |
|---|--------------------------|
| 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 | : Not available |
| Particle characteristics | : Ní bhaineann le hábhar |

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 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) | : Tocsaineach má shlogtar. |
| Acute toxicity (dermal) | : Marfach i dteagmháil leis an gcráiceann. |
| Acute toxicity (inhalation) | : () |

1-Phenylpiperazine (92-54-6)

| | |
|-----------------------|--------------------------------|
| LD50 ó bhéal francach | 210 mg/kg (RTECS No TM2625000) |
| LD50 dermal rat | 149 mg/kg |

| | |
|--|--|
| Creimeadh/greannú craicinn | : Causes severe skin burns. |
| Damáiste/greannú tromchúiseach súl | : Ina chúis le damáiste tromchúiseach don tsúil. |
| Íoghrú riospráide nó craicinn | : () |
| Só-ghineacht ghaiméite | : () |
| Carcanaigineacht | : () |
| Tocsaineacht atáirgthe | : () |
| Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) | : () |
| Tocsaineacht sain-spriocorgáin (ilnochtadh) | : () |
| Guais asúite | : () |

Levodropropizine impurity B

Bileog Sonraí Sábháilteachta

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

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)

12.2. Inchoimeádachas agus díghráiditheacht

1-Phenylpiperazine (92-54-6)

| | |
|---------------------------------------|------------------------|
| Inchoimeádachas agus díghráiditheacht | 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

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 | | |
| UN 2922 | UN 2922 | UN 2922 |
| 14.2. Ainm seolta ceart UN | | |
| CORROSIVE LIQUID, TOXIC, N.O.S. | CORROSIVE LIQUID, TOXIC, N.O.S. | Corrosive liquid, toxic, n.o.s. |
| Transport document description | | |
| UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S., 8 (6.1), II, (E) | UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S., 8 (6.1), II | UN 2922 Corrosive liquid, toxic, n.o.s., 8 (6.1), II |
| 14.3. Aicme nó aicmí guaise iompair | | |
| 8 (6.1) | 8 (6.1) | 8 (6.1) |

Levodropropizine impurity B

Bileog Sonraí Sábháilteachta

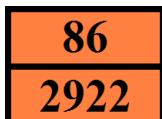
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| ADR | IMDG | IATA |
|---|---|---|
|  |  |  |
| 14.4. Grúpa pacála | | |
| II | II | II |
| 14.5. Guaiseacha comhshaoil | | |
| Contúirteach don chomhshaoil: No | Contúirteach don chomhshaoil: No Truailleán mara: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-B | Contúirteach don chomhshaoil: No |

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

| | |
|---|---------------|
| Classification code (ADR) | : CT1 |
| Special provisions (ADR) | : 274 |
| Limited quantities (ADR) | : 1I |
| Excepted quantities (ADR) | : E2 |
| Packing instructions (ADR) | : P001, IBC02 |
| Mixed packing provisions (ADR) | : MP15 |
| Portable tank and bulk container instructions (ADR) | : T7 |
| Portable tank and bulk container special provisions (ADR) | : TP2 |
| Tank code (ADR) | : L4BN |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 2 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13, CV28 |
| Hazard identification number (Kemler No.) | : 86 |
| Orange plates | : |



Tunnel restriction code (ADR) : E

Iompar ar muir

| | |
|------------------------------------|--|
| Special provision (IMDG) | : 274 |
| Limited quantities (IMDG) | : 1 L |
| Excepted quantities (IMDG) | : E2 |
| Packing instructions (IMDG) | : P001 |
| IBC packing instructions (IMDG) | : IBC02 |
| Tank instructions (IMDG) | : T7 |
| Tank special provisions (IMDG) | : TP2 |
| Stowage category (IMDG) | : B |
| Stowage and handling (IMDG) | : SW2 |
| Properties and observations (IMDG) | : Causes burns to skin, eyes and mucous membranes. Toxic if swallowed, by skin contact or by inhalation. |

Aeriompar

| | |
|--|----------------|
| PCA Excepted quantities (IATA) | : E2 |
| PCA Limited quantities (IATA) | : Y840 |
| PCA limited quantity max net quantity (IATA) | : 0.5L |
| PCA packing instructions (IATA) | : 851 |
| PCA max net quantity (IATA) | : 1L |
| CAO packing instructions (IATA) | : 855 |
| CAO max net quantity (IATA) | : 30L |
| Special provisions (IATA) | : A3, A4, A803 |

Levodropropizine impurity B

Bileog Sonraí Sábhálteachta

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

ERG code (IATA) : 8P

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

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 sábhálteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

CUID 16: Faisnéis eile

| Léiriú ar na hathruithe | | |
|-------------------------|---------------------------------------|----------|
| Cuid | Changed item | Comments |
| | (ADR) (RID) | Added |
| | Number of blue cones/lights (ADN) | Added |
| | Ventilation (ADN) | Added |
| | Equipment required (ADN) | Added |
| | Carriage permitted (ADN) | Added |
| | Excepted quantities (ADN) | Added |
| | Limited quantities (ADN) | Added |
| | Danger labels (ADN) | Added |
| | Classification code (ADN) | Added |
| | Proper Shipping Name (RID) | Added |
| | Hazard identification number (RID) | Added |
| | Colis express (express parcels) (RID) | Added |

Levodropropizine impurity B

Bileog Sonraí Sábháilteachta

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

| Léiriú ar na hathruithe | | |
|-------------------------|---|----------|
| Cuid | Changed item | Comments |
| | Special provisions for carriage - Loading, unloading and handling (RID) | Added |
| | Transport category (RID) | Added |
| | Tank codes for RID tanks (RID) | Added |
| | Portable tank and bulk container special provisions (RID) | Added |
| | Portable tank and bulk container instructions (RID) | Added |
| | Mixed packing provisions (RID) | Added |
| | Packing instructions (RID) | Added |
| | Excepted quantities (RID) | Added |
| | Limited quantities (RID) | Added |
| | Special provisions (RID) | Added |
| | Packing group (RID) | Added |
| | Classification code (RID) | Added |
| | ERG code (IATA) | Added |
| | Special provisions (IATA) | Added |
| | CAO max net quantity (IATA) | Added |
| | CAO packing instructions (IATA) | Added |
| | PCA max net quantity (IATA) | Added |
| | PCA packing instructions (IATA) | Added |
| | PCA limited quantity max net quantity (IATA) | Added |
| | PCA Limited quantities (IATA) | Added |
| | PCA Excepted quantities (IATA) | Added |
| | Danger labels (IATA) | Added |
| | Proper Shipping Name (IATA) | Added |
| | Properties and observations (IMDG) | Added |
| | Proper Shipping Name (IMDG) | Added |
| | Danger labels (IMDG) | Added |
| | EmS-No. (Spillage) | Added |
| | EmS-No. (Fire) | Added |
| | Limited quantities (IMDG) | Added |
| | Stowage and handling (IMDG) | Added |
| | Stowage category (IMDG) | Added |
| | Tank special provisions (IMDG) | Added |
| | Tank instructions (IMDG) | Added |
| | IBC packing instructions (IMDG) | Added |
| | Excepted quantities (IMDG) | Added |
| | Special provision (IMDG) | Added |

Levodropropizine impurity B

Bileog Sonraí Sábhálteachta

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

| Léiriú ar na hathruithe | | |
|-------------------------|---|-----------------|
| Cuid | Changed item | Comments |
| | Special provisions for carriage - Loading, unloading and handling (ADR) | Added |
| | Tank code (ADR) | Added |
| | Portable tank and bulk container special provisions (ADR) | Added |
| | Portable tank and bulk container instructions (ADR) | Added |
| | Mixed packing provisions (ADR) | Added |
| | Packing instructions (ADR) | Added |
| | Vehicle for tank carriage | Added |
| | Supersedes version of | Added |
| | Dáta athbheithnithe | Added |
| | Dáta eisiúna | Modified |
| 1.2 | Restrictions on use | Modified |
| 1.2 | Úsáid na substainte / an mheascáin | Modified |
| 1.2 | Príomhchatagóir úsáide | Removed |
| 2.1 | Éifeachtaí díobhálacha fisiceimiceacha, um shláinte an duine agus um an comhshaol | Modified |
| 2.1 | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP] | Modified |
| 2.2 | Ráitis réamhchúraim (CLP) | Modified |
| 2.2 | Hazard statements (CLP) | Modified |
| 2.2 | Hazard pictograms (CLP) | Modified |
| 2.2 | Signal word (CLP) | Modified |
| 2.3 | Faisnéis eile | Added |
| 4.1 | Beartha garchabhrach tar éis iontógála | Added |
| 4.1 | Beartha garchabhrach tar éis ionanáilaithe | Added |
| 4.1 | First-aid measures general | Added |
| 4.1 | Beartha garchabhrach tar éis teagmhála leis an gcráiceann | Modified |
| 4.1 | Beartha garchabhrach tar éis teagmhála leis an tsúil | Modified |
| 4.2 | Siomptóim/gortuithe tar éis ionanáilaithe | Added |
| 4.2 | Siomptóim/gortuithe tar éis iontógála | Added |
| 4.2 | Siomptóim/gortuithe tar éis teagmhála leis an tsúil | Added |
| 4.2 | Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann | Added |
| 5.1 | Meáin mhí-oiriúnacha um múchadh | Added |
| 5.1 | Meáin oiriúnacha um múchadh | Modified |

Levodropropizine impurity B

Bileog Sonraí Sábhálteachta

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

| Léiriú ar na hathruithe | | |
|-------------------------|---|----------|
| Cuid | Changed item | Comments |
| 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 | Protective equipment | Added |
| 6.1 | Bearta ginearálta | Added |
| 6.1 | Emergency procedures | Modified |
| 6.2 | Réamhchúraimí comhshaoil | Added |
| 6.3 | I gcomhair srianta | Added |
| 6.3 | Modhanna um ghlanadh | Added |
| 6.4 | Reference to other sections (8, 13) | Added |
| 7.1 | Réamhchúraimí maidir le láimhseáil shábháilte | Added |
| 7.1 | Bearta sláinteachais | Added |
| 7.2 | Packaging materials | Added |
| 7.2 | Coinníollacha stórála | Added |
| 7.3 | Specific end uses | Removed |
| 8.2 | Cosaint súl | Added |
| 8.2 | Cosaint riospráide | 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 |
| 9 | Splancphointe | 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 |
| 11.1 | LD50 dermal rat | Added |
| 11.1 | ATE CLP (dermal) | Added |
| 11.1 | ATE CLP (oral) | Modified |
| 11.1 | LD50 ó bhéal francach | Modified |
| 14.1 | (ADR) (ADN) | Added |
| 14.1 | (ADR) (IMDG) | Added |
| 14.1 | (ADR) (IATA) | Added |
| 14.1 | (ADR) (ADR) | Added |

Levodropropizine impurity B

Bileog Sonraí Sábháilteachta

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

| Léiriú ar na hathruithe | | |
|-------------------------|---|----------|
| Cuid | Changed item | Comments |
| 14.2 | Proper Shipping Name (ADN) | Added |
| 14.2 | Proper Shipping Name (ADR) | Added |
| 14.3 | Danger labels (RID) | Added |
| 14.3 | Danger labels (ADR) | Added |
| 14.3 | Class (ADR) | Added |
| 14.4 | Packing group (ADN) | Added |
| 14.4 | Packing group (IATA) | Added |
| 14.4 | Packing group (IMDG) | Added |
| 14.4 | Packing group (ADR) | Added |
| 14.6 | Special provisions (ADN) | Added |
| 14.6 | Packing instructions (IMDG) | Added |
| 14.6 | Transport category (ADR) | Added |
| 14.6 | Special provisions (ADR) | Added |
| 14.6 | Excepted quantities (ADR) | Added |
| 14.6 | Limited quantities (ADR) | Added |
| 14.6 | Tunnel restriction code (ADR) | Added |
| 14.6 | Hazard identification number (Kemler No.) | Added |
| 14.6 | Classification code (ADR) | Added |

| Full text of H- and EUH-statements: | |
|-------------------------------------|---|
| Acute Tox. 2 (Deirmeach) | Géarthocsaineacht (dheirmeach), Catagóir 2 |
| Acute Tox. 3 (Bhéil) | Géarthocsaineacht (bhéil), Catagóir 3 |
| Eye Dam. 1 | Damáiste tromchúiseach don tsúil/greannú súl, Catagóir 1 |
| H301 | Tocsaineach má shlogtar. |
| H310 | Marfach i dteagmháil leis an gcaiceann. |
| H314 | Ina chúis le dóna tromchúiseacha craicinn agus le damáiste don tsúil. |
| H318 | Ina chúis le damáiste tromchúiseach don tsúil. |
| Skin Corr. 1B | Creimeadh/greannú craicinn, Catagóir 1B |

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. 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 product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.