

Clobetasone butyrate for system suitability

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 04/11/2025 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 | : Clobetasone butyrate for system suitability |
| Chemical name | : Clobetasone butyrate |
| Uimh. CE | : 246-635-9 |
| Uimh. CAS | : 25122-57-0 |
| Cód an táirge | : 202500352 |

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]

| | |
|--|--------|
| Suaiteoir inchríneach maidir leis an gcomhshaoil, Catagóir 2 | EUH431 |
| Suaiteoir inchríneach maidir le sláinte an duine, Catagóir 1 | EUH380 |
| Tocsaineacht atáirgeach, Catagóir 1B | H360 |
| Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 2 | H373 |
| Full text of H- and EUH-statements: see section 16 | |

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

D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh.

2.2. Eilimintí lipéid

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

Hazard pictograms (CLP)



GHS08

Signal word (CLP) : Contúirt

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| | |
|----------------------------|--|
| Hazard statements (CLP) | : EUH380 - D'fhéadfadh sé a bheith ina chúis le suaitheadh inchríneach sa duine. EUH431 - Ceaptar go bhfuil sé ina chúis le suaitheadh inchríneach sa chomhshaoil. H360 - D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. H373 - D'fhéadfadh sé damáiste a dhéanamh d'orgáin (endocrine system) trí nochtadh fada nó ilnochtadh. |
| Ráitis réamhchúiraim (CLP) | : P201 - Faigh treoracha speisialta roimh úsáid. P202 - Ná láimhsigh go dtí go léifear agus go dtuigfear gach ráiteas réamhchúiraim sábháilteachta. P260 - Ná hanálaigh deannach/múch/gás/ceo/gala/sprae. P263 - Seachain teagmháil le linn toirchis agus fad agus atá an chíos á tabhairt. P273 - Ná scaoiltear amach sa chomhshaoil. P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe. P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn. 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)



GHS08

2.3. Guaiseacha eile

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

| Ainm | Sainitheantóir táirge | | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP] |
|--|--|-------|--|
| Clobetasone butyrate substance identified as having endocrine disrupting properties | Uimh. CAS: 25122-57-0 Uimh. CE: 246-635-9 | ≤ 100 | ED ENV 2, EUH431 ED HH 1, EUH380 Repr. 1B, H360 STOT RE 2, H373 |

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 ggraceann | : 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. Faigh comhairle/cúram liachta láithreach. |

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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.

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 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. 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

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Réamhchúraimí 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.

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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

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 | : white, almost white. |
| Dealramh | : Powder. |
| Molecular mass | : 479 g/mol |
| Boladh | : Not available |
| Tairseach bolaidh | : Not available |
| Leáphointe | : ≈ 178 °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 | : Uisce: < 0.1 g/l |

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| | |
|---|--------------------------|
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Partition coefficient n-octanol/water (Log Pow) | : < 4 |
| 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

10.5. Ábhair neamh-chomhoiriúnacha

Níl aon fhaisnéis bhreise ar fáil

10.6. Táirgí dian-scaoilte 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) | : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.) |
| Acute toxicity (dermal) | : () |
| Acute toxicity (inhalation) | : () |

| Clobetasone butyrate (25122-57-0) | |
|--|---|
| LD50 ó bhéal francach | > 6000 mg/kg (RTECS No TU4154083) |
| Creimeadh/greannú craicinn | : () |
| Damáiste/greannú tromchúiseach súl | : () |
| Íoghrú riospráide nó craicinn | : () |
| Só-ghineacht ghaiméite | : () |
| Carcanaigineacht | : () |
| Tocsaineacht atáirgthe | : D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. |
| Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) | : () |
| Tocsaineacht sain-spriocorgáin (ilnochtadh) | : D'fhéadfadh sé damáiste a dhéanamh d'orgáin (endocrine system) trí nochtadh fada nó ilnochtadh. |
| Guais asúite | : () |

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11.2. Information on other hazards

Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

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

Clobetasone butyrate (25122-57-0)

| | |
|---------------------------------------|------------------------|
| Inchoimeádachas agus díghráiditheacht | Not rapidly degradable |
|---------------------------------------|------------------------|

12.3. Acmhainneacht bhithbhailitheacht

Clobetasone butyrate (25122-57-0)

| | |
|---|-----|
| Partition coefficient n-octanol/water (Log Pow) | < 4 |
|---|-----|

12.4. Soghluasteacht san ithir

Níl aon fhaisnéis bhreise ar fáil

12.5. Torthaí an mheasúnaithe PBT agus vPvB

Clobetasone butyrate (25122-57-0)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system.

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 | | |
| Neamhrialaithe | | |

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| ADR | IMDG | IATA |
|--|---------------|---------------|
| 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

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

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CUID 16: Faisnéis eile

Full text of H- and EUH-statements:

| | |
|-----------|---|
| ED ENV 2 | Suaiteoir inchríneach maidir leis an gcomhshaol, Catagóir 2 |
| ED HH 1 | Suaiteoir inchríneach maidir le sláinte an duine, Catagóir 1 |
| EUH380 | D'fhéadfadh sé a bheith ina chúis le suaitheadh inchríneach sa duine. |
| EUH431 | Ceaptar go bhfuil sé ina chúis le suaitheadh inchríneach sa chomhshaol. |
| H360 | D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. |
| H373 | D'fhéadfadh sé damáiste a dhéanamh d'orgáin (endocrine system) trí nochtadh fada nó ilnochtadh. |
| Repr. 1B | Tocsaineacht atáirgeach, Catagóir 1B |
| STOT RE 2 | Tocsaineacht sain-spriocorgáin – Athnochtadh, Catagóir 2 |

Safety Data Sheet (SDS), EU

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