

Fluticasone furoate

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 01/04/2023 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 : Fluticasone furoate
Chemical name : Fluticasone furoate
Cód an táirge : 202000208

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
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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]

Tocsaineacht atáirgeach, Catagóir 1B H360Df
Tocsaineacht sain-spricorgáin – Athnochtadh, Catagóir 2 H373
Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1 H410
Full text of H- and EUH-statements: see section 16

Éifeachtaí díobhála 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) :



GHS08

GHS09

Signal word (CLP) :

Hazard statements (CLP) :

Ráitis réamhchúraim (CLP) :

Contúirt
H360Df - D'fhéadfadh sé damáiste a dhéanamh don leanbh sa bhroinn. Meastar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht.
H373 - D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh.
H410 - An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.
P201 - Faigh treoracha speisialta roimh úsáid.
P202 - Ná láimhsigh go dtí go léifear agus go dtuigfear gach ráiteas réamhchúraim sábháilteachta.

Fluticasone furoate

Bileog Sonraí Sábháilteachta

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

- P260 - Ná hanálaigh deannach/múch/gás/ceo/gala/sprae.
P273 - Ná scaoiltear amach sa chomhshaol.
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

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] |
|---------------------|-----------------------|-------|--|
| Fluticasone furoate | - | ≤ 100 | Repr. 1B, H360Df STOT RE 2, H373 Aquatic Chronic 1, H410 |

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 ionanáilthe : 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. Specific medical surveillance. 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.
Siomptóim/gortuithe tar éis ionanáilthe : 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.
Siomptóim/gortuithe tar éis iontógála : Symptoms may include dizziness, headache, nausea and loss of coordination.

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. Active substance. Pharmaceutical.

Fluticasone furoate

Bileog Sonraí Sábháilteachta

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

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 neamhlú

Technical measures : Comply with applicable regulations.

Coinníollacha stórála : Stóráil faoi ghlas.

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

Fluticasone furoate

Bileog Sonraí Sábháilteachta

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

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 nochta

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 |
| Dealramh | : Powder. |
| Boladh | : Ní bhaineann le hábhar. |
| 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 |

Fluticasone furoate

Bileog Sonraí Sábháilteachta

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

| | |
|---|--------------------------|
| Slaodacht, cinéimiteach | : Ní bhaineann le hábhar |
| Intuaslagthacht | : Uisce: < 0.1 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

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) | : Not classified (Lack of data) |
| Acute toxicity (dermal) | : Not classified (Lack of data) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |
| Creimeadh/greannú craicinn | : Not classified (Lack of data) |
| Damáiste/greannú tromchúiseach súl | : Not classified (Lack of data) |
| Íoghrú riospráide nó craicinn | : Not classified (Lack of data) |
| Só-ghineacht ghaiméite | : Not classified (Lack of data) |
| Carcanaigineacht | : Not classified (Lack of data) |
| Tocsaineacht atáirgthe | : D'fhéadfadh sé damáiste a dhéanamh don leanbh sa bhroinn. Meastar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht. |
| Tocsaineacht sain-spricorgáin (aon nochtadh amháin) | : Not classified (Lack of data) |
| Tocsaineacht sain-spricorgáin (ilnochtadh) | : D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| Guais asúite | : Not classified (Technical impossibility to obtain the data) |

Fluticasone furoate

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

Éiceolaíocht - ginearálta : Hazardous waste. Use suitable disposal containers.
Guaiseach don chomhshaol uisceach, ghearrthéarmach (géarghuais) : Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) : An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.

Fluticasone furoate

| | |
|----------------------|-------------------------------------|
| EC50 - Crustacea [1] | ≥ 4.2 mg/l (48h, (OECD 202 method)) |
|----------------------|-------------------------------------|

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

12.7. Éifeachtaí díobhálacha eile

Níl aon fhaisnéis bhreise ar fáil

CUID 13: Breithníthe diúscartha

13.1. Modhanna cóireála dramhaíola

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

CUID 14: Faisnéis Iompair




In accordance with ADR / IMDG / IATA

| ADR | IMDG | IATA |
|--|--|--|
| 14.1. UN number or ID number | | |
| UN 3077 | UN 3077 | UN 3077 |
| 14.2. Ainm seolta ceart UN | | |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | Environmentally hazardous substance, solid, n.o.s. |

Fluticasone furoate



Bileog Sonraí Sábháilteachta

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

| ADR | IMDG | IATA |
|---|--|---|
| Transport document description | | |
| UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-) | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT | UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III |
| 14.3. Aicme nó aicmí guaise iompair | | |
| 9 | 9 | 9 |
|  |  |  |
| 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) | : M7 |
| Special provisions (ADR) | : 274, 335, 375, 601 |
| Limited quantities (ADR) | : 5kg |
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P002, IBC08, LP02, R001 |
| Packing provisions (ADR) | : PP12, B3 |
| Mixed packing provisions (ADR) | : MP10 |
| Portable tank and bulk container instructions (ADR) | : T1, BK1, BK2, BK3 |
| Portable tank and bulk container special provisions (ADR) | : TP33 |
| Tank code (ADR) | : SGAV, LGBV |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 3 |
| Special provisions for carriage - Packages (ADR) | : V13 |
| Special provisions for carriage - Bulk (ADR) | : VC1, VC2 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13 |
| Hazard identification number (Kemler No.) | : 90 |
| Orange plates | :   |
| Tunnel restriction code (ADR) | : - |

Iompar ar muir

| | |
|---------------------------------|---------------------------|
| Special provision (IMDG) | : 274, 335, 966, 967, 969 |
| Limited quantities (IMDG) | : 5 kg |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : LP02, P002 |
| Packing provisions (IMDG) | : PP12 |
| IBC packing instructions (IMDG) | : IBC08 |
| IBC special provisions (IMDG) | : B3 |
| Tank instructions (IMDG) | : BK1, BK2, BK3, T1 |
| Tank special provisions (IMDG) | : TP33 |
| EmS-No. (Fire) | : F-A |
| EmS-No. (Spillage) | : S-F |

Fluticasone furoate

Bileog Sonraí Sábháilteachta

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

Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

Aeriompar

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg
Special provisions (IATA) : A97, A158, A179, A197, A215
ERG code (IATA) : 9L

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

CUID 16: Faisnéis eile

Full text of H- and EUH-statements:

Aquatic Chronic 1

Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1

Fluticasone furoate

Bileog Sonraí Sábháilteachta

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

| Full text of H- and EUH-statements: | |
|-------------------------------------|---|
| H360Df | D'fhéadfadh sé damáiste a dhéanamh don leanbh sa bhroinn. Meastar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht. |
| H373 | D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| H410 | An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |
| Repr. 1B | Tocsaineacht atáirgeach, Catagóir 1B |
| 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.