

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 03/04/2023 Dáta athbheithnithe: 04/11/2025 Supersedes version of: 03/04/2023 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	: Clobetasone butyrate
Chemical name	: Clobetasone butyrate
Uimh. CE	: 246-635-9
Uimh. CAS	: 25122-57-0
Cód an táirge	: 201600219

#### 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
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#### 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](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Uimhir ghutháin éigeandála

Uimhir éigeandála	: +33(0)390215608
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### 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

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

- Hazard statements (CLP) : EUH380 - D'fhéadfadh sé a bheith ina chúis le suaithéadh inchríneach sa duine.  
EUH431 - Ceaptar go bhfuil sé ina chúis le suaithéadh 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 chíoach 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

- Faisnéis eile : Active substance (in pharmaceutical products).  
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]
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 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 iontóigála : 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.

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

### 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.

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

### 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)

##### 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

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

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	: ()

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

### 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 díghrádaitheacht

#### Clobetasone butyrate (25122-57-0)

Inchoimeádachas agus díghrádaitheacht	Not rapidly degradable
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### 12.3. Acmhainneacht bhithbhailitheach

#### Clobetasone butyrate (25122-57-0)

Partition coefficient n-octanol/water (Log Pow)	< 4
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### 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
<b>14.1. UN number or ID number</b>		
Neamhrialaithe		

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

ADR	IMDG	IATA
<b>14.2. Ainm seolta ceart UN</b>		
Not regulated	Not regulated	Not regulated
<b>14.3. Aicme nó aicmí guaise iompair</b>		
Not regulated	Not regulated	Not regulated
<b>14.4. Grúpa pacála</b>		
Not regulated	Not regulated	Not regulated
<b>14.5. Guaiseacha comhshaoil</b>		
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

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

### CUID 16: Faisnéis eile

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
	Adverse health effects caused by endocrine disrupting properties	<b>Added</b>
	Supersedes version of	<b>Added</b>
	Dáta athbhreithnithe	<b>Added</b>
1.1	Uimh. CE	<b>Added</b>
1.1	Uimh. CAS	<b>Added</b>
1.1	Synonyms	<b>Removed</b>
1.1	Ainm	<b>Modified</b>
1.2	Restrictions on use	<b>Modified</b>
1.2	Úsáid na substainte / an mheascáin	<b>Modified</b>
1.2	Príomhchatagóir úsáide	<b>Removed</b>
2.1	Éifeachtaí díobhálacha fisiciceimiceacha, um shláinte an duine agus um an comhshaol	<b>Modified</b>
2.1	Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.2	Ráitis réamhchúraim (CLP)	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.3	Faisnéis eile	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	Beartha garchabhrach tar éis teagmhála leis an gcráiceann	<b>Modified</b>
4.1	Beartha garchabhrach tar éis ionanáilaithe	<b>Added</b>
4.1	Beartha garchabhrach tar éis iontóigála	<b>Added</b>
4.1	Beartha garchabhrach tar éis teagmhála leis an tsúil	<b>Modified</b>
5.1	Meáin mhí-oiriúnacha um múchadh	<b>Added</b>
5.1	Meáin oiriúnacha um múchadh	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Guais dóiteáin	<b>Removed</b>
5.3	Cosaint i rith comhrac dóiteáin	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.1	Beartha ginearálta	<b>Added</b>
6.2	Réamhchúraimí comhshaoil	<b>Added</b>
6.3	I gcomhair srianta	<b>Added</b>
6.3	Modhanna um ghlanadh	<b>Added</b>

# Clobetasone butyrate

## 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
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Added
7.1	Réamhchúraimí maidir le láimhseáil shábháilte	Added
7.1	Bearta sláinteachais	Added
7.2	Coinníollacha stórála	Added
7.2	Packaging materials	Added
7.3	Specific end uses	Removed
8.2	Cosaint riospráide	Added
8.2	Cosaint lámha	Modified
8.2	Cosaint súl	Added
8.2	Rialuithe iomchuí innealtóireachta	Modified
8.2	Cosaint chraicinn agus choirp	Modified
9	Molecular mass	Added
9	Leáphointe	Added
9	Dath	Added
9	Partition coefficient n-octanol/water (Log Pow)	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 ó bhéal francach	Modified
12.1	Éiceolaíocht - ginearálta	Removed
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added

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 suaithheadh inchríneach sa duine.
EUH431	Ceaptar go bhfuil sé ina chúis le suaithheadh 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

# Clobetasone butyrate

## Bileog Sonraí Sábháilteachta

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

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