

# Bambuterol impurity mixture

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 03/04/2023 Leagan: 1.0

### CUID 1: Sainaitheantóir na substainte / an mheascáin agus na cuideachta / an ghnóthais

#### 1.1. Sainaitheantóir táirge

Foirm an táirge : Meascán  
Product name : Bambuterol impurity mixture  
Cód an táirge : 201900130

#### 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  
EDQM, Council of Europe 7, Allée Kastner, CS30026  
F- 67081 Strasbourg  
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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

### 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  
Tocsaineacht sain-spricorgáin – Athnochtadh, Catagóir 2 H373  
Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 3 H412  
Full text of H- and EUH-statements: see section 16

##### Éifeachtaí díobhálacha 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) :



GHS07

GHS08

Signal word (CLP) :

Rabhadh

Contains :

3-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-5-hydroxyphenyl dimethylcarbamate; 5-[(1RS)-1-hydroxyethyl]-1,3-phenylene bis(dimethylcarbamate)

Hazard statements (CLP) :

H302 - Díobhálach má shlogtar.  
H373 - D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh.  
H412 - Díobhálach don saol uisceach, le héifeachtaí fadtréimhseacha.

Ráitis réamhchúraim (CLP) :

P260 - Ná hanálaigh dust/vapours.  
P301+P312 - MÁ SHLOGTAR: Cuir glao ar IONAD NIMHE nó ar dhochtúir/lia má

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bhraitheann tú tinn.

P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP)

:



GHS08

Hazardous ingredients

: 3-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-5-hydroxyphenyl dimethylcarbamate; 5-[(1RS)-1-hydroxyethyl]-1,3-phenylene bis(dimethylcarbamate)

### 2.3. Guaiseacha eile

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not 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 at a concentration equal to or greater than 0,1 %

## CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

### 3.1. Substaint

Ní bhaineann le hábhar

### 3.2. Meascán

| Ainm   | Sainitheantóir táirge |      | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]   |
|--|-----------------------|------|--|
| 5-[(1RS)-1-hydroxyethyl]-1,3-phenylene bis(dimethylcarbamate)                  | -                     | 68.1 | Acute Tox. 4 (Bhéil), H302 (ATE=500 mg/kg meáchan coirp)   |
| 3-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-5-hydroxyphenyl dimethylcarbamate | -                     | 31.9 | Acute Tox. 4 (Bhéil), H302 (ATE=500 mg/kg meáchan coirp)<br>STOT RE 2, H373<br>Aquatic Chronic 3, H412 |

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

## CUID 4: Bearta garchabhrach

### 4.1. Cur síos ar na bearta garchabhrach

Bearta garchabhrach tar éis teagmhála leis an gcráiceann : Wipe off as much as possible (using a clean, soft, absorbent material).

Bearta garchabhrach tar éis teagmhála leis an tsúil : Rinse eyes with water as a precaution.

### 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 : Extinguishing blanket.

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### 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

#### 6.1.1. Do phearsanra neamh-éigeandála

Emergency procedures : Seachain gach nochtadh gan ghá.

#### 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

Níl aon fhaisnéis bhreise ar fáil

### 6.4. Tagairt do chodanna eile

Níl aon fhaisnéis bhreise ar fáil

## CUID 7: Láimhseáil agus stóráil

### 7.1. Réamhchúraimí maidir le láimhseáil shábháilte

Níl aon fhaisnéis bhreise ar fáil

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

Níl aon fhaisnéis bhreise ar fáil

### 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

#### 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

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### 8.2. Rialuithe nochta

#### 8.2.1. Appropriate engineering controls

##### Rialuithe iomchuí innealtóireachta:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

#### 8.2.2. Personal protection equipment

##### 8.2.2.1. Eye and face protection

Níl aon fhaisnéis bhreise ar fáil

##### 8.2.2.2. Skin protection

##### Cosaint chraicinn agus choirp:

Lab coat

##### Cosaint lámha:

Protective gloves

##### 8.2.2.3. Respiratory protection

Níl aon fhaisnéis bhreise ar fáil

##### 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          |
| Boladh  | : Not available          |
| 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          |
| Slaodacht, cinéimiteach                         | : Ní bhaineann le hábhar |
| 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                     | : 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

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### 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

None known.

### 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 dianscaoilte 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)       | : Díobhálach má shlogtar. |
| Acute toxicity (dermal)     | : Not classified          |
| Acute toxicity (inhalation) | : Not classified          |

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|--|--|
| ATE CLP (oral)   | 500 mg/kg meáchan coirp  |
| Creimeadh/greannú craicinn   | : Not classified   |
| Damáiste/greannú tromchúiseach súl   | : Not classified   |
| Íoghrú riospráide nó craicinn  | : Not classified   |
| Só-ghineacht ghaiméite   | : Not classified   |
| Carcanaigineacht   | : Not classified   |
| Tocsaineacht atáirgthe   | : Not classified   |
| Tocsaineacht sain-spríocorgáin (aon nochtadh amháin)                           | : Not classified   |
| Tocsaineacht sain-spríocorgáin (ilnochtadh)                                    | : D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| 3-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-5-hydroxyphenyl dimethylcarbamate |  |
| Tocsaineacht sain-spríocorgáin (ilnochtadh)                                    | D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh.   |
| Guais asúite   | : Not classified   |

### 11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

## CUID 12: Faisnéis éiceolaíochta

### 12.1. Tocsaineacht

Éiceolaíocht - ginearálta : Presents no specific risk for the environment.

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Guaiseach don chomhshaol uisceach, : Not classified  
ghearrthéarmach (géarghuais)

Guaiseach don chomhshaol uisceach, fadtéarmach : Díobhálach don saol uisceach, le héifeachtaí fadtréimhseacha.  
(guais ainsealach)

### 12.2. Inchoimeádachas agus díghráiditheacht

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: 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                   |
|--|------------------------|------------------------|
| <b>14.1. UN number or ID number</b>        |                        |                        |
| Ní bhaineann le hábhar                     | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| <b>14.2. Ainm seolta ceart UN</b>          |                        |                        |
| Ní bhaineann le hábhar                     | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| <b>14.3. Aicme nó aicmí guaise iompair</b> |                        |                        |
| Ní bhaineann le hábhar                     | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| <b>14.4. Grúpa pacála</b>                  |                        |                        |
| Ní bhaineann le hábhar                     | Ní bhaineann le hábhar | Ní bhaineann le hábhar |
| <b>14.5. Guaiseacha comhshaoil</b>         |                        |                        |
| 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

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### 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

#### 15.1.1. Rialacháin de chuid an AE

##### REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

##### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Contains no substance(s) 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)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

##### 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:

|                      |  |
|----------------------|--|
| Acute Tox. 4 (Bhéil) | Géarthocsaineacht (bhéil), Catagóir 4  |
| Aquatic Chronic 3    | Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 3           |
| H302                 | Díobhálach má shlogtar.  |
| H373                 | D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| H412                 | Díobhálach don saol uisceach, le héifeachtaí fadtréimhseacha.                |
| STOT RE 2            | Tocsaineacht sain-spriocorgáin – Athnochtadh, Catagóir 2                     |

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

|                      |      |                    |
|----------------------|------|--------------------|
| Acute Tox. 4 (Bhéil) | H302 | Calculation method |
|----------------------|------|--------------------|

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### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

|                   |      |                    |
|-------------------|------|--------------------|
| STOT RE 2         | H373 | Calculation method |
| Aquatic Chronic 3 | H412 | Calculation method |

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.