

# Dinoprostone

## 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: Sainaitheant na substainte / an mheascáin agus na cuideachta / an ghnóthais

#### 1.1. Sainaitheantóir táirge

|                 |  |
|-----------------|--|
| Foirm an táirge | : Substance  |
| Substance name  | : Dinoprostone   |
| Cód an táirge   | : 201600301  |
| Synonyms        | : Dinoprostone, salts, hydrates, isomers and impurities where applicable |

#### 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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#### 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 |
| Géarthocsaineacht (ionanál), Catagóir 4                  | H332 |
| Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 1 | H372 |
| 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)   | : Contúirt   |
| Hazard statements (CLP)   | : H302+H332 - Ábhar dochrach má shlogtar nó má ionanálaítear é.<br>H372 - Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh. |
| Ráitis réamhchúraim (CLP)   | : P260 - Ná hanáiligh deannach.<br>P301+P312 - MÁ SHLOGTAR: Cuir glao ar ar dhochtúir mura mbraitheann tú go maith.                  |
| Labelling according to: exemption for inner packaging where the contents do not exceed 10ml |  |

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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]  |
|--------------|-----------------------|-------|---|
| Dinoprostone | -                     | ≤ 100 | Acute Tox. 4 (Bhéil), H302 (ATE=300 mg/kg meáchan coirp)<br>Acute Tox. 4 (Ionanál), H332 (ATE=1.5 mg/l/4h)<br>STOT RE 1, H372 |

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 ionanáilithe                 | : 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). Nigh le neart uisce/....     |
| Bearta garchabhrach tar éis teagmhála leis an tsúil      | : Rinse with water while holding the eyes wide open.   |
| Bearta garchabhrach tar éis iontóigála                   | : 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 ionanáilithe                 | : 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 iontóigála                   | : 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.

## CUID 5: Bearta comhrac dóiteáin

### 5.1. Meáin múchta

Meáin oiriúnacha um múchadh : Extinguishing blanket.

### 5.2. Guaiseacha speisialta a eascraíonn as an substaint nó as an meascán

Guais dóiteáin : See Heading 2.2.

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### 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 neamhlúí

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

#### 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

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### 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           |
| Slaodacht, cinéimiteach                         | : Ní bhaineann le hábhar  |
| Intuaslaghacht                                  | : 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  |

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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 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) : Díobhálach má ionanálaítear.

| Dinoprostone   |  |
|--|--|
| LD50 ó bhéal francach                                | 300 – 2000 mg/kg   |
| Creimeadh/greannú craicinn                           | : Not classified (Lack of data)  |
| Damáiste/greannú tromchúiseach súl                   | : Not classified (Lack of data)  |
| Íogru riospráide nó craicinn                         | : Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.) |
| Só-ghineacht ghaiméite                               | : Not classified (Lack of data)  |
| Carcanaigineacht                                     | : Not classified (Lack of data)  |
| Tocsaineacht atáirgthe                               | : Not classified (Further details: Géarthocsaineacht)                                    |
| Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) | : Not classified (Further details: Géarthocsaineacht)                                    |
| Tocsaineacht sain-spriocorgáin (ilnochtadh)          | : Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.                             |
| Guais asúite   | : Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.) |

### 11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

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### CUID 12: Faisnéis éiceolaíochta

#### 12.1. Tocsaineacht

Éiceolaíocht - ginearálta : Hazardous waste. Use suitable disposal containers.  
Guaiseach don chomhshaol uisceach, ghearrthéarmach (géarghuais) : Not classified  
Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) : Not classified

#### 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: Breithnithe 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                   |
|--|------------------------|------------------------|
| <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 |

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### 14.6. Réamhchúraimí speisialta don úsáideoir

#### Iompar ar talamh

Ní bhaineann le hábhar

#### Iompar ar muir

Ní bhaineann le hábhar

#### 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)

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:

|                        |   |
|------------------------|---|
| Acute Tox. 4 (Bhéil)   | Géarthocsaineacht (bhéil), Catagóir 4   |
| Acute Tox. 4 (Ionanál) | Géarthocsaineacht (ionanál), Catagóir 4 |
| H302                   | Díobhálach má shlogtar.                 |
| H332                   | Díobhálach má ionanálaítear.            |

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### Full text of H- and EUH-statements:

|           |  |
|-----------|--|
| H372      | Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh. |
| STOT RE 1 | Tocsaineacht sain-spriocorgáin – Athnochtadh, Catagóir 1   |

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.