

# Metronidazole impurity A

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 03/04/2023 Dáta athbheithnithe: 20/02/2026 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	: Metronidazole impurity A
Chemical name	: 2-Methyl-4(5)-nitroimidazole
Uimh. CE	: 211-790-3
Uimh. CAS	: 696-23-1
Cód an táirge	: 202100303

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

##### Éifeachtaí díobhálacha fisiceimiceacha, um shláinte an duine agus um an comhshaol

Díobhálach má shlogtar.

#### 2.2. Eilimintí lipéid

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Rabhadh

Hazard statements (CLP) : H302 - Díobhálach má shlogtar.  
Ráitis réamhchúraim (CLP) : P264 - Nigh ... go lánchúramach tar éis láimhsithe.  
P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid.  
P301+P312 - MÁ SHLOGTAR: Cuir glao ar IONAD NIMHE nó ar dhoctúir má bhraitheann

# Metronidazole impurity A

## Bileog Sonraí Sábháilteachta

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

tú tinn.  
P330 - Sruthlaítear an béal.  
P501 - Diúscair an t-ábhar/an coimeádán i ...

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

No labelling required

### 2.3. Guaiseacha eile

Faisnéis eile : 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]
2-Methyl-4(5)-nitroimidazole	Uimh. CAS: 696-23-1 Uimh. CE: 211-790-3	≤ 100	Acute Tox. 4 (Bhéil), H302 (ATE=1540 mg/kg)

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. Cuir glao láithreach ar IONAD NIMHE/ar dhoctóir.

### 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.

# Metronidazole impurity A

## Bileog Sonraí Sábhálteachta

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

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

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.

#### 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 nocht / cosaint phearsanta

#### 8.1. Paraiméadair rialaithe

Níl aon fhaisnéis bhreise ar fáil

#### 8.2. Rialuithe nocht

##### 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.

# Metronidazole impurity A

## Bileog Sonraí Sábháilteachta

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

### 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	: Not available
Molecular mass	: 127.1 g/mol
Boladh	: Not available
Tairseach bolaidh	: Not available
Leáphointe	: Not available
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	: 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

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

# Metronidazole impurity A

## Bileog Sonraí Sábhálteachta

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

### 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 dianscaoilte 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) : Díobhálach má shlogtar.  
Acute toxicity (dermal) : ()  
Acute toxicity (inhalation) : ()

#### 2-Methyl-4(5)-nitroimidazole (696-23-1)

LD50 ó bhéal francach	1540 mg/kg
-----------------------	------------

Creimeadh/greannú craicinn : ()  
Damáiste/greannú tromchúiseach súl : ()  
Íoghrú riospráide nó craicinn : ()  
Só-ghineacht ghaiméite : ()  
Carcanaigineacht : ()  
Tocsaineacht atáirgthe : ()  
Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) : ()  
Tocsaineacht sain-spriocorgáin (ilnochtadh) : ()  
Guais asúite : ()

### 11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

## 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

#### 2-Methyl-4(5)-nitroimidazole (696-23-1)

Inchoimeádachas agus díghrádaitheacht	Not rapidly degradable
---------------------------------------	------------------------

### 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

# Metronidazole impurity A

## Bileog Sonraí Sábhálteachta

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

### 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>		
Neamhrialaithe		
<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 sábhálteacht, 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)

# Metronidazole impurity A

## Bileog Sonraí Sábhálteachta

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

### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

### Rialachán 2024/590 maidir le substaintí a ídíonn an ciseal ózóin

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

### 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)

Not listed on the Explosives Precursors list (EU)

### Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

## 15.2. Measúnú sábhálteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

## CUID 16: Faisnéis eile

### Léiriú ar na hathruithe:

Aicmiú na substainte nó an mheascáin.

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
	Supersedes version of	Added
	Dáta athbhreithnithe	Added
1.1	Uimh. CE	Added
1.1	Uimh. CAS	Added
1.1	Synonyms	Removed
1.1	Ainm	Modified
1.2	Restrictions on use	Modified
1.2	Úsáid na substainte / an mheascáin	Modified
1.2	Príomhchatagóir úsáide	Removed
2.1	Éifeachtaí díobhálacha fisiciceimiceacha, um shláinte an duine agus um an comhshaol	Modified
2.3	Faisnéis eile	Added
4.1	First-aid measures general	Added
4.1	Bearta garchabhrach tar éis teagmhála leis an gcráiceann	Modified
4.1	Bearta garchabhrach tar éis ionanáilaithe	Added
4.1	Bearta garchabhrach tar éis iontóigála	Added
4.1	Bearta garchabhrach tar éis teagmhála leis an tsúil	Modified
5.1	Meáin mhí-oiriúnacha um múchadh	Added
5.1	Meáin oiriúnacha um múchadh	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Guais dóiteáin	Removed

# Metronidazole impurity A

## Bileog Sonraí Sábhálteachta

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

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
5.3	Cosaint i rith comhrac dóiteáin	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.1	Bearta ginearálta	Added
6.2	Réamhchúraimí comhshaoil	Added
6.3	I gcomhair srianta	Added
6.3	Modhanna um ghlanadh	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Réamhchúraimí maidir le láimhseáil shábhálte	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
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	Added
11.1	ATE CLP (oral)	Modified
12.1	Éiceolaíocht - ginearálta	Removed

Full text of H- and EUH-statements:	
Acute Tox. 4 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 4
H302	Díobhálach má shlogtar.

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. 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 product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

# Metronidazole impurity A

## Bileog Sonraí Sábhálteachta

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

---