

# Trimetazidine for peak identification

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 10/10/2025 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	: Trimetazidine for peak identification
Chemical name	: Trimetazidine dihydrochloride
Uimh. CE	: 236-117-0
Uimh. CAS	: 13171-25-0
Cód an táirge	: 202500731

#### 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]

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 glo ar IONAD NIMHE nó ar dhochtúir má bhraitheann tú tinn.

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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

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]
Trimetazidine dihydrochloride	Uimh. CAS: 13171-25-0 Uimh. CE: 236-117-0	≤ 100	Acute Tox. 4 (Bhéil), H302 (ATE=1700 mg/kg meáchan coirp)

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 iontógála	: 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 dhoctúir.

### 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.
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### 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.

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### CUID 6: Bearta i gcás scaoileadh de thaisme

#### 6.1. Réamhchúiraimí 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. Réamhchúiraimí 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. Réamhchúiraimí maidir le láimhseáil shábháilte

Réamhchúiraimí 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 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)

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### 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	: 339.26 g/mol
Boladh	: Not available
Tairseach bolaidh	: Not available
Leáphointe	: 225 – 228 °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: 100 – 1000 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

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

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### 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) : ()

#### Trimetazidine dihydrochloride (13171-25-0)

LD50 ó bhéal francach	1700 mg/kg
Creimeadh/greannú craicinn	: ()
Damáiste/greannú tromchúiseach súl	: ()
Íoghrú riospráide nó craicinn	: ()
Só-ghineacht ghaiméite	: (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Carcanaigineacht	: ()
Tocsaineacht atáirgthe	: (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
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

#### Trimetazidine dihydrochloride (13171-25-0)

Inchoimeádachas agus díghrádaitheacht	Not rapidly degradable
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### 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

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### 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		
<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)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

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### 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

## CUID 16: Faisnéis eile

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

Acute Tox. 4 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 4
H302	Díobhálach má shlogtar.

Safety Data Sheet (SDS), EU

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