

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 23/02/2024 Dáta athbhreithnithe: 08/01/2026 Supersedes version of: 23/02/2024 Leagan: 2.0

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

1.1. Sainaitheantóir táirge

Foirm an táirge	: Substance
Substance name	: Colchicine for system suitability B
Chemical name	: Colchicine
Uimh. innéacs CE	: 614-005-00-6
Uimh. CE	: 200-598-5
Uimh. CAS	: 64-86-8
Cód an táirge	: 202400006

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, 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]

Só-ghineacht ghaiméite, Catagóir 1B	H340
Géarthocsaineacht (bhéil), Catagóir 2	H300
Full text of H- and EUH-statements: see section 16	

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

Marfach má shlogtar. D'fhéadfadh sé a bheith ina chúis le héalanga géiniteacha.

2.2. Eilimintí lipéid

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

Hazard pictograms (CLP)



GHS06

GHS08

Signal word (CLP)

: Contúirt

Hazard statements (CLP)

: H340 - D'fhéadfadh sé a bheith ina chúis le héalanga géiniteacha.
H300 - Marfach má shlogtar.

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

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

Ráitis réamhchúraim (CLP)	: P201 - Faigh treoracha speisialta roimh úsáid. P202 - Ná láimhsigh go dtí go léifear agus go dtuigfear gach ráiteas réamhchúraim sábháilteachta. P264 - Nigh ... go láimhreach tar éis láimhsithe. P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid. P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe. P301+P310 - MÁ SHLOGTAR: Cuir glao láithreach ar IONAD NIMHE nó ar dhochtúir. P308+P313 - I gCÁS nochta nó má mheastar a bheith nochtaithe: Faigh comhairle/cúram liachta. P321 - Cóir liachta ar leith (féach threoir gharchabhrach forlíontach ar an lipéad seo). P330 - Sruthlaítear an béal. P405 - Stóráil faoi ghlas. P501 - Diúscair an t-ábhar/an coimeádán i ...
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Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)	:  
	GHS06 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

Faisnéis eile	: Active substance (in pharmaceutical products). Warning - substance not yet tested completely.
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CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

Ainm	Sainitheantóir táirge		Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]
Colchicine	Uimh. CAS: 64-86-8 Uimh. CE: 200-598-5 Uimh. innéacs CE: 614-005-00-6	≤ 100	Muta. 1B, H340 Acute Tox. 2 (Bhéil), H300 (ATE=26 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 coinneigh 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 dhochtúir.

4.2. Na siomptóim agus na héifeachtaí is tábhachtaí, idir shiomptóim ghéarmhíochaine agus shiomptóim mhoillithe

Siomptóim/gortuithe tar éis iontógála	: Marfach má shlogtar.
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Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

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

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. 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

- | | |
|--|---|
| Additional hazards when processed | : Do not expose pregnant or breastfeeding women. |
| 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 neamhlúí

- | | |
|-----------------------|---|
| 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. |

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

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

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	: yellowish-white.
Dealramh	: Powder.
Molecular mass	: 399.4 g/mol
Boladh	: Not available
Tairseach bolaidh	: Not available
Leáphointe	: $\approx 157^{\circ}\text{C}$
Reophointe	: Not available
Fiuchphointe	: Not available
Inadhaiteacht	: 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: $> 1000\text{ g/l}$
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

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

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

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 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) : Marfach má shlogtar.
Acute toxicity (dermal) : ()
Acute toxicity (inhalation) : ()

Colchicine (64-86-8)	
LD50 ó bhéal francach	26 mg/kg

Creimeadh/greannú craicinn : ()
Damáiste/greannú tromchúiseach súl : ()
Íoghrú riospráide nó craicinn : ()
Só-ghineacht ghaiméite : D'fhéadfadh sé a bheith ina chúis le héalanga géiniteacha.
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)

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

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

Guaiseach don chomhshaol uisceach, fadtéarmach : ()
(guais ainsealach)

12.2. Inchoimeádachas agus díghrádaitheacht

Colchicine (64-86-8)	
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

Colchicine (64-86-8)	
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

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
14.1. UN number or ID number		
UN 1544	UN 1544	UN 1544
14.2. Ainm seolta ceart UN		
ALKALOIDS, SOLID, N.O.S.	ALKALOIDS, SOLID, N.O.S.	Alkaloids, solid, n.o.s.
Transport document description		
UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1, II, (D/E)	UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1, II	UN 1544 Alkaloids, solid, n.o.s., 6.1, II
14.3. Aicme nó aicmí guaise iompair		
6.1	6.1	6.1

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

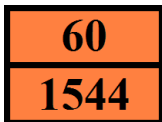
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.4. Grúpa pacála		
II	II	II
14.5. Guaiseacha comhshaoil		
Contúirteach don chomhshaoil: No	Contúirteach don chomhshaoil: No Truailleán mara: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-A	Contúirteach don chomhshaoil: No

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

Classification code (ADR)	: T2
Special provisions (ADR)	: 43, 274
Limited quantities (ADR)	: 500g
Excepted quantities (ADR)	: E4
Packing instructions (ADR)	: P002, IBC08
Packing provisions (ADR)	: B4
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAH, L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Packages (ADR)	: V11
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9, S19
Hazard identification number (Kemler No.)	: 60
Orange plates	:



Tunnel restriction code (ADR)	: D/E
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Iompar ar muir

Special provision (IMDG)	: 43, 274
Limited quantities (IMDG)	: 500 g
Excepted quantities (IMDG)	: E4
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B21, B4
Tank instructions (IMDG)	: T3
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: A wide range of toxic solids, generally of vegetable origin. Toxic if swallowed, by skin contact or by inhalation.

Aeriompar

PCA Excepted quantities (IATA)	: E4
PCA Limited quantities (IATA)	: Y644
PCA limited quantity max net quantity (IATA)	: 1kg
PCA packing instructions (IATA)	: 669
PCA max net quantity (IATA)	: 25kg
CAO packing instructions (IATA)	: 676
CAO max net quantity (IATA)	: 100kg
Special provisions (IATA)	: A3, A5, A6, A801
ERG code (IATA)	: 6L

Colchicine for system suitability B

Bileog Sonraí Sábháilteachta

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

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

Rialachán 2024/590 maidir le substaintí a idionn an ciseal ózón

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 sábháilteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

CUID 16: Faisnéis eile

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
	Packing provisions (ADR)	Modified
	Special provisions (IATA)	Modified
	Supersedes version of	Added
	Dáta athbhreithnithe	Added
1.2	Príomhchatagóir úsáide	Removed
1.2	Restrictions on use	Modified
1.2	Úsáid na substainte / an mheascáin	Modified
2.1	Éifeachtaí díobhálacha fisiceimiceacha, um shláinte an duine agus um an comhshaoil	Modified
2.2	Ráitis réamhchúraim (CLP)	Modified
3	Comhdhéanamh / faisnéis faoi chomhábhair	Modified
4.1	Bearta garchabhrach tar éis iontógála	Modified
4.1	Bearta garchabhrach tar éis teagmhála leis an tsúil	Modified

Colchicine for system suitability B

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
4.1	Bearta garchabhrach tar éis teagmhála leis an gcráiceann	Modified
4.1	Bearta garchabhrach tar éis ionanáilaithe	Modified
4.1	First-aid measures general	Added
4.2	Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann	Removed
4.2	Siomptóim/gortuithe tar éis ionanáilaithe	Removed
4.2	Siomptóim/gortuithe tar éis teagmhála leis an tsúil	Removed
4.2	Symptoms/effects	Removed
4.2	Siomptóim/gortuithe tar éis iontógála	Modified
4.3	Other medical advice or treatment	Removed
5.1	Meáin oiriúnacha um múchadh	Modified
5.1	Meáin mhí-oiriúnacha um múchadh	Added
5.2	Guais dóiteáin	Removed
5.2	Hazardous decomposition products in case of fire	Added
5.3	Cosaint i rith comhrac dóiteáin	Added
5.3	Firefighting instructions	Modified
6.1	Bearta ginearálta	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.2	Réamhchúraimí comhshaoil	Added
6.3	I gcomhair srianta	Added
6.3	Modhanna um ghlanadh	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Bearta sláinteachais	Modified
7.1	Additional hazards when processed	Modified
7.1	Réamhchúraimí maidir le láimhseáil shábháilte	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.2	Coinníollacha stórála	Modified
7.3	Specific end uses	Removed
8.2	Cosaint súl	Modified
8.2	Rialuithe iomchuí innealtóireachta	Modified
8.2	Cosaint chraicinn agus choirp	Modified
8.2	Cosaint riospráide	Modified
8.2	Cosaint lámha	Modified
9	Boladh	Removed

Colchicine for system suitability B

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
9	Molecular mass	Added
9	Leáphointe	Added
9	Dath	Added
10.1	Imoibríocht	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
13.1	Regional waste regulation	Removed
13.1	Product/Packaging disposal recommendations	Removed
14.2	Proper Shipping Name (ADR)	Modified

Full text of H- and EUH-statements:	
Acute Tox. 2 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 2
Muta. 1B	Só-ghineacht ghaiméite, Catagóir 1B
H300	Marfach má shlogtar.
H340	D'fhéadfadh sé a bheith ina chúis le héalanga géiniteacha.

Safety Data Sheet (SDS), EU

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