

Meloxicam impurity B

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 21/08/2024 Leagan: 1.0

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

1.1. Sainaitheantóir táirge

| | |
|------------------|----------------------------|
| Foirm an táirge | : Substance |
| Substance name | : Meloxicam impurity B |
| Chemical name | : 2-amino-5-methylthiazole |
| Uimh. innéacs CE | : 613-308-00-0 |
| Uimh. CE | : 423-800-5 |
| Uimh. CAS | : 7305-71-7 |
| Cód an táirge | : 202400414 |

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

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EDQM, Council of Europe
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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 |
|-------------------|-------------------|

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-spríocorgáin – Athnochtadh, Catagóir 2 | H373 |
| Guaiseach don timpeallacht uisceach – Ghéarghuais, Catagóir H400 1 | H400 |
| Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1 | H410 |

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

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

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

2.2. Eilimintí lipéid

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

Hazard pictograms (CLP)



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| | |
|---------------------------|---|
| Signal word (CLP) | : Rabhadh |
| Hazard statements (CLP) | : H302 - Díobhálach má shlogtar. H373 - D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. H410 - An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |
| Ráitis réamhchúraim (CLP) | : P260 - Ná hanálaigh deannach/múch/gás/ceo/gala/sprae. P264 - Nigh ... go lánchúramach tar éis láimhsithe. P270 - Ná hith, ná hól agus ná caitear tobac agus an táirge seo á úsáid. P273 - Ná scaoiltear amach sa chomhshaol. P301+P312 - MÁ SHLOGTAR: Cuir glao ar IONAD NIMHE nó ar dhoctúir má bhraitheann tú tinn. P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn. P330 - Sruthlaítear an béal. P391 - Bailigh doirteadh. P501 - Diúscair an t-ábhar/an coimeádán i ... |

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

Hazard pictograms (CLP)



GHS08

2.3. Guaiseacha eile

Faisnéis eile : Warning - substance not yet tested completely.

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substant

| Ainm | Sainaitheantóir táirge | | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP] |
|--------------------------|---|-------|---|
| 2-amino-5-methylthiazole | Uimh. CAS: 7305-71-7 Uimh. CE: 423-800-5 Uimh. innéacs CE: 613-308-00-0 | ≤ 100 | Acute Tox. 4 (Bhéil), H302 (ATE=688 mg/kg meáchan coirp) STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |

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 ggraiceann | : 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

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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. 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 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.

7.3. Úsáid shonrach deiridh nó úsáid sonracha deiridh

Níl aon fhaisnéis bhreise ar fáil

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CUID 8: Rialuithe nochtá / cosaint phearsanta

8.1. Paraiméadair rialaithe

Níl aon fhaisnéis bhreise ar fáil

8.2. Rialuithe nochtá

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 | : Not available |
| Boladh | : Not available |
| Tairseach bolaidh | : Not available |
| Leáphointe | : ≈ 93 °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: 10 – 33.3 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

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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 dian-scaoilte 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) : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Acute toxicity (inhalation) : ()

2-amino-5-methylthiazole (7305-71-7)

| | |
|-----------------------|--------------|
| LD50 ó bhéal francach | 688 mg/kg |
| LD50 dermal rat | > 2000 mg/kg |

Creimeadh/greannú craicinn : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Damáiste/greannú tromchúiseach súl : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Íoghrú riospráide nó craicinn : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Só-ghineacht ghaiméite : (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Carcanaigineacht : ()
Tocsaineacht atáirgthe : ()
Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) : ()
Tocsaineacht sain-spriocorgáin (ilnochtadh) : D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó 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) : An-tocsaineach don saol uisceach.
Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) : An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.

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| 2-amino-5-methylthiazole (7305-71-7) | |
|--------------------------------------|--|
| LC50 - Fish [1] | 190 mg/l (96 Hours, Brachydanio rerio (zebra-fish)) (Test method EU C.1) |
| EC50 - Crustacea [1] | 0.7 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method) |
| ErC50 algae | 136.2 mg/l (72 Hours, Desmodesmus subspicatus) (Test method EU C.3) |
| NOEC chronic algae | 10.6 mg/l (72 Hours, Desmodesmus subspicatus) (Test method EU C.3) |

12.2. Inchoimeádachas agus díghráiditheacht

| 2-amino-5-methylthiazole (7305-71-7) | |
|---------------------------------------|------------------------|
| Inchoimeádachas agus díghráiditheacht | 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

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 3077 | UN 3077 | UN 3077 |
| 14.2. Ainm seolta ceart UN | | |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | Environmentally hazardous substance, solid, n.o.s. |
| Transport document description | | |
| UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-) | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT | UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III |
| 14.3. Aicme nó aicmí guaise iompair | | |
| 9 | 9 | 9 |

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

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

| | |
|---|---|
| Classification code (ADR) | : M7 |
| Special provisions (ADR) | : 274, 335, 375, 601 |
| Limited quantities (ADR) | : 5kg |
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P002, IBC08, LP02, R001 |
| Packing provisions (ADR) | : PP12, B3 |
| Mixed packing provisions (ADR) | : MP10 |
| Portable tank and bulk container instructions (ADR) | : T1, BK1, BK2, BK3 |
| Portable tank and bulk container special provisions (ADR) | : TP33 |
| Tank code (ADR) | : SGAV, LGBV |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 3 |
| Special provisions for carriage - Packages (ADR) | : V13 |
| Special provisions for carriage - Bulk (ADR) | : VC1, VC2 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13 |
| Hazard identification number (Kemler No.) | : 90 |
| Orange plates | :  |
| Tunnel restriction code (ADR) | : - |

Iompar ar muir

| | |
|---------------------------------|---------------------------|
| Special provision (IMDG) | : 274, 335, 966, 967, 969 |
| Limited quantities (IMDG) | : 5 kg |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : LP02, P002 |
| Packing provisions (IMDG) | : PP12 |
| IBC packing instructions (IMDG) | : IBC08 |
| IBC special provisions (IMDG) | : B3 |
| Tank instructions (IMDG) | : BK1, BK2, BK3, T1 |
| Tank special provisions (IMDG) | : TP33 |
| Stowage category (IMDG) | : A |
| Stowage and handling (IMDG) | : SW23 |

Aeriompar

| | |
|--|---------|
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y956 |
| PCA limited quantity max net quantity (IATA) | : 30kgG |
| PCA packing instructions (IATA) | : 956 |
| PCA max net quantity (IATA) | : 400kg |

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| | |
|---------------------------------|-------------------------------|
| CAO packing instructions (IATA) | : 956 |
| CAO max net quantity (IATA) | : 400kg |
| Special provisions (IATA) | : A97, A158, A179, A197, A215 |
| ERG code (IATA) | : 9L |

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

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 (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)

15.2. Measúnú sábhálteachta 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 Acute 1 | Guaiseach don timpeallacht uisceach – Ghéarghuais, Catagóir 1 |
| Aquatic Chronic 1 | Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1 |
| H302 | Díobhálach má shlogtar. |
| H373 | D'fhéadfadh sé damáiste a dhéanamh d'orgáin trí nochtadh fada nó ilnochtadh. |
| H400 | An-tocsaineach don saol uisceach. |
| H410 | An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |
| STOT RE 2 | Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 2 |

Safety Data Sheet (SDS), EU

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