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

1.1. Sainaitheantóir táirge

Foirm an táirge	:	Substance
Substance name	:	Piroxicam
Chemical name	:	4-Hydroxy-2-methyl-N-(pyridin-2-yl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide
Cód an táirge	:	201600732

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
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

CUID 2: Aithint guaiseacha

2.1. Aicmiú na substainte nó an mheascáin

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

Géarthocsaineacht (bhéil), Catagóir 3	H301
Tocsaineacht atáirgeach, Catagóir 2	H361
Tocsaineacht sain-spriocorgáin – Athnochtadh, Catagóir 1	H372

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

Éifeachtaí díobhálacha fisiciceimiceacha, 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) :

GHS06 GHS08

Signal word (CLP)	:	Contúirt
Hazard statements (CLP)	:	H301 - Tocsaineach má shlogtar. H361 - Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. H372 - Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.
Ráitis réamhchúraim (CLP)	:	P201 - Faigh treoracha speisialta roimh úsáid. P202 - Ná láimhsigh go dtí go léifear agus go dtuigfear gach ráiteas réamhchúraim sábháilteachta.

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.
P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe.
P301+P310 - MÁ SHLOGTAR: Cuir glao láithreach ar dhoctúir.
P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn.
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 ...

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

Hazard pictograms (CLP) :

GHS06 GHS08

2.3. Guaiseacha eile

Níl aon fhaisnéis bhreise ar fáil

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

Ainm	Sainaitheantóir táirge		Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]
4-Hydroxy-2-methyl-N-(pyridin-2-yl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide	-	≤ 100	Acute Tox. 3 (Bhéil), H301 (ATE=216 mg/kg meáchan coirp) Repr. 2, H361 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 ionanálaithe : Move to fresh air. Allow affected person to breathe fresh air.
Bearta garchabhrach tar éis teagmhála leis an gcraiceann : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
Bearta garchabhrach tar éis teagmhála leis an tsúil : Rinse with water while holding the eyes wide open.
Bearta garchabhrach tar éis iontógála : Sruthlaítear an béal. Cuir glao láithreach ar IONAD NIMHE/ar dhoctúir. 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 ionanálaithe : Insufficient data available.
Siomptóim/gortuithe tar éis teagmhála leis an gcraiceann : Insufficient data available.
Siomptóim/gortuithe tar éis teagmhála leis an tsúil : Insufficient data available.
Siomptóim/gortuithe tar éis iontógála : 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 tsubstaint nó as an meascán

Guais dóiteáin : See Heading 2.2.

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 neamhluí

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 nochta / 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

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
Intuaslagthacht	:	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
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)	:	Tocsaineach má shlogtar.
Acute toxicity (dermal)	:	Not classified (Lack of data)
Acute toxicity (inhalation)	:	Not classified (Lack of data)

4-Hydroxy-2-methyl-N-(pyridin-2-yl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide	
LD50 ó bhéal francach	216 mg/kg RTECS No

Creimeadh/greannú craicinn	:	Not classified (Lack of data)
Damáiste/greannú tromchúiseach súl	:	Not classified (Lack of data)
Íogrú riospráide nó craicinn	:	Not classified (Lack of data)
Só-ghineacht ghaiméite	:	Not classified (Lack of data)
Carcanaigineacht	:	Not classified (Lack of data)
Tocsaineacht atáirgthe	:	Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
Tocsaineacht sain-spriocorgáin (aon nochtadh amháin)	:	Not classified (Lack of data)
Tocsaineacht sain-spriocorgáin (ilnochtadh)	:	Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.

Guais asúite : Not classified (Technical impossibility to obtain the data)

11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

CUID 12: Faisnéis éiceolaíochta

12.1. Tocsaineacht

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

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 waste regulation : Dispose in a safe manner in accordance with local/national regulations.
Product/Packaging disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

CUID 14: Faisnéis Iompair

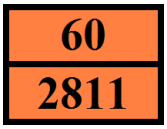
In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 2811	UN 2811	UN 2811
14.2. Ainm seolta ceart UN		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
Transport document description		
UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E)	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III	UN 2811 Toxic solid, organic, n.o.s., 6.1, III

ADR	IMDG	IATA
14.3. Aicme nó aicmí guaise iompair		
6.1	6.1	6.1
14.4. Grúpa pacála		
III	III	III
14.5. Guaiseacha comhshaoil		
Contúirteach don chomhshaol: No	Contúirteach don chomhshaol: No Truailleán mara: No	Contúirteach don chomhshaol: No

14.6. Réamhchúraimí speisialta don úsáideoir

Iompar ar talamh

Classification code (ADR)	:	T2
Special provisions (ADR)	:	274, 614
Limited quantities (ADR)	:	5kg
Excepted quantities (ADR)	:	E1
Packing instructions (ADR)	:	P002, IBC08, LP02, R001
Packing provisions (ADR)	:	B3
Mixed packing provisions (ADR)	:	MP10
Portable tank and bulk container instructions (ADR)	:	T1
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 - Bulk (ADR)	:	VC1, VC2, AP7
Special provisions for carriage - Loading, unloading and handling (ADR)	:	CV13, CV28
Special provisions for carriage - Operation (ADR)	:	S9
Hazard identification number (Kemler No.)	:	60
Orange plates	:	
Tunnel restriction code (ADR)	:	E

Iompar ar muir

Special provision (IMDG)	:	223, 274
Limited quantities (IMDG)	:	5 kg
Excepted quantities (IMDG)	:	E1
Packing instructions (IMDG)	:	P002
IBC packing instructions (IMDG)	:	IBC08
IBC special provisions (IMDG)	:	B3
Tank instructions (IMDG)	:	T1
Tank special provisions (IMDG)	:	TP33
EmS-No. (Fire)	:	F-A
EmS-No. (Spillage)	:	S-A
Stowage category (IMDG)	:	A
Properties and observations (IMDG)	:	Toxic if swallowed, by skin contact or by inhalation.

Aeriompar

PCA Excepted quantities (IATA)	:	E1

PCA Limited quantities (IATA)	:	Y645
PCA limited quantity max net quantity (IATA)	:	10kg
PCA packing instructions (IATA)	:	670
PCA max net quantity (IATA)	:	100kg
CAO packing instructions (IATA)	:	677
CAO max net quantity (IATA)	:	200kg
Special provisions (IATA)	:	A3, A5
ERG code (IATA)	:	6L

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

Léiriú ar na hathruithe

Cuid	Changed item	Change	Comments
	Supersedes version of	Added	
	Dáta athbhreithnithe	Added	
2.1	Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]	Modified	

Léiriú ar na hathruithe			
Cuid	**Changed item**	**Change**	**Comments**
2.2	Hazard pictograms (CLP)	Modified	
2.2	Ráitis réamhchúraim (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
4.1	Bearta garchabhrach tar éis teagmhála leis an gcraiceann	Modified	
4.1	Bearta garchabhrach tar éis iontógála	Modified	
4.2	Symptoms/effects	Added	
6.1	Emergency procedures	Added	
6.3	Modhanna um ghlanadh	Modified	
7.1	Réamhchúraimí maidir le láimhseáil shábháilte	Modified	
11.1	Reason for no classification	Added	
11.1	LD50 ó bhéal francach	Added	
11.1	Reason for no classification	Modified	
11.1	ATE CLP (oral)	Modified	
12.1	Reason for no classification	Added	
13.1	Product/Packaging disposal recommendations	Added	

Full text of H- and EUH-statements:	
Acute Tox. 3 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 3
H301	Tocsaineach má shlogtar.
H361	Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
H372	Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.
Repr. 2	Tocsaineacht atáirgeach, Catagóir 2
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.