

Erlotinib impurity mixture

Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Dáta eisiúna: 06/10/2023 Leagan: 1.0

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

1.1. Sainaitheantóir táirge

Foirm an táirge : Meascán
Product name : Erlotinib impurity mixture
Cód an táirge : 202300419

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

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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
Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 2 H411
Full text of H- and EUH-statements: see section 16

Éifeachtaí díobhálacha fisiceimiceacha, 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)



GHS07

GHS09

Signal word (CLP)

: Rabhadh

Contains

: 6,7-bis(2-methoxyethoxy)quinazolin-4(3H)-one ; 4-chloro-6-(2-chloroethoxy)-7-(2-methoxyethoxy)quinazoline; 7-(2-Chloroethoxy)-N-(3-ethynylphenyl)-6-(2-methoxyethoxy)quinazolin-4-amine hydrochloride

Hazard statements (CLP)

: H302 - Díobhálach má shlogtar.
H411 - Tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.

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.
P273 - Ná scaoiltear amach sa chomhshaol.
P301+P312 - MÁ SHLOGTAR: Cuir glao ar IONAD NIMHE nó ar dhochtúir má bhraitheann

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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

Hazardous ingredients : 6,7-bis(2-methoxyethoxy)quinazolin-4(3H)-one ; 4-chloro-6-(2-chloroethoxy)-7-(2-methoxyethoxy)quinazoline; 7-(2-Chloroethoxy)-N-(3-ethynylphenyl)-6-(2-methoxyethoxy)quinazolin-4-amine hydrochloride

2.3. Guaiseacha eile

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

CUID 3: Comhdhéanamh / faisnéis faoi chomhábhair

3.1. Substaint

Ní bhaineann le hábhar

3.2. Meascán

Ainm	Sainaitheantóir táirge		Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]
4-chloro-6-(2-chloroethoxy)-7-(2-methoxyethoxy)quinazoline	-	≥ 40 - ≤ 60	Acute Tox. 4 (Bhéil), H302 (ATE=500 mg/kg meáchan coirp) Aquatic Chronic 2, H411
6,7-bis(2-methoxyethoxy)quinazolin-4(3H)-one	-	≥ 20 - ≤ 30	Acute Tox. 4 (Bhéil), H302 (ATE=500 mg/kg meáchan coirp) Aquatic Chronic 2, H411
7-(2-Chloroethoxy)-N-(3-ethynylphenyl)-6-(2-methoxyethoxy)quinazolin-4-amine hydrochloride	-	≥ 20 - ≤ 30	Acute Tox. 4 (Bhéil), H302 (ATE=500 mg/kg meáchan coirp) Aquatic Chronic 2, H411

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

CUID 4: Bearta garchabhrach

4.1. Cur síos ar na bearta garchabhrach

Bearta garchabhrach tar éis teagmhála leis an : Wipe off as much as possible (using a clean, soft, absorbent material).

gcráiceann

Bearta garchabhrach tar éis teagmhála leis an tsúil : Rinse eyes with water as a precaution.

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 : Extinguishing blanket.

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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

6.1.1. Do phearsanra neamh-éigeandála

Emergency procedures : Seachain gach nochtadh gan ghá.

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

Níl aon fhaisnéis bhreise ar fáil

6.4. Tagairt do chodanna eile

Níl aon fhaisnéis bhreise ar fáil

CUID 7: Láimhseáil agus stóráil

7.1. Réamhchúraimí maidir le láimhseáil shábháilte

Níl aon fhaisnéis bhreise ar fáil

7.2. Coinníollacha stórála sábháilte, lena n-áirítear aon neamhlúí

Níl aon fhaisnéis bhreise ar fáil

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

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8.2. Rialuithe nochta

8.2.1. Appropriate engineering controls

Rialuithe iomchuí innealtóireachta:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Níl aon fhaisnéis bhreise ar fáil

8.2.2.2. Skin protection

Cosaint chraicinn agus choirp:

Lab coat

Cosaint lámha:

Protective gloves

8.2.2.3. Respiratory protection

Níl aon fhaisnéis bhreise ar fáil

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
Boladh	: Not available
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	: 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

9.2.1. Information with regard to physical hazard classes

Níl aon fhaisnéis bhreise ar fáil

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9.2.2. Other safety characteristics

Níl aon fhaisméir bhreise ar fáil

CUID 10: Cobhsaíocht agus imoibríocht

10.1. Imoibríocht

Stable under normal conditions.

10.2. Cobhsaíocht cheimiceach

Níl aon fhaisméir bhreise ar fáil

10.3. D'fhéadfadh a bheith ina chúis le fhrithghníomhartha guaiseacha

None known.

10.4. Coinníollacha lena seachaint

Níl aon fhaisméir 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)	: Díobhálach má shlogtar.
Acute toxicity (dermal)	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Acute toxicity (inhalation)	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)

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ATE CLP (oral)	500 mg/kg meáchan coirp
6,7-bis(2-methoxyethoxy)quinazolin-4(3H)-one	
LD50 ó bhéal francach	300 – 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LD50 deirmeach coinín	> 2000 mg/kg
4-chloro-6-(2-chloroethoxy)-7-(2-methoxyethoxy)quinazoline	
LD50 ó bhéal francach	300 – 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LD50 deirmeach coinín	> 2000 mg/kg
7-(2-Chloroethoxy)-N-(3-ethynylphenyl)-6-(2-methoxyethoxy)quinazolin-4-amine hydrochloride	
LD50 ó bhéal francach	300 – 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LD50 deirmeach coinín	> 2000 mg/kg

Creimeadh/greannú craicinn	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Damáiste/greannú tromchúiseach súl	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Íoghrú riospráide nó craicinn	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Só-ghineacht ghaiméite	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)

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Carcanaigineacht	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Tocsaineacht atáirgthe	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Tocsaineacht sain-spriocorgáin (aon nochtadh amháin)	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Tocsaineacht sain-spriocorgáin (ilnochtadh)	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Guais asúite	: Not classified (Technical impossibility to obtain the data)

11.2. Information on other hazards

Níl aon fhaiseánis bhreise ar fáil

CUID 12: Faisnéis éiceolaíochta

12.1. Tocsaineacht

Éiceolaíocht - ginearálta	: Presents no specific risk for the environment.
Guaiseach don chomhshaol uisceach, ghearrthéarmach (géarghuais)	: Not classified (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach)	: Tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.
Not rapidly degradable	

12.2. Inchoimeádachas agus díghrádaitheacht

Níl aon fhaiseánis bhreise ar fáil

12.3. Acmhainneacht bhithbhailitheach

Níl aon fhaiseánis bhreise ar fáil

12.4. Soghluaisteacht san ithir

Níl aon fhaiseánis bhreise ar fáil

12.5. Torthaí an mheasúnaithe PBT agus vPvB

Níl aon fhaiseánis bhreise ar fáil

12.6. Endocrine disrupting properties

Níl aon fhaiseánis bhreise ar fáil

12.7. Éifeachtaí díobhálacha eile

Níl aon fhaiseánis bhreise ar fáil

CUID 13: Breithnithe diúscartha

13.1. Modhanna cóireála dramhaíola

Níl aon fhaiseánis 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.

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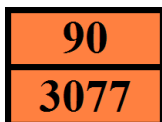
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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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
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 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)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) 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)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

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

Full text of H- and EUH-statements:

Acute Tox. 4 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 4
Aquatic Chronic 2	Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 2

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Full text of H- and EUH-statements:

H302	Díobhálach má shlogtar.
H411	Tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Acute Tox. 4 (Bhéil)	H302	Calculation method
Aquatic Chronic 2	H411	Calculation method

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.