

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 08/11/2024 Leagan: 1.0

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

#### 1.1. Sainaitheantóir táirge

|                 |                                                                                                                                |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|
| Foirm an táirge | : Substance                                                                                                                    |
| Substance name  | : Regorafenib impurity D                                                                                                       |
| Chemical name   | : 3,7-difluoro-N,N'-dimethyl-5-oxo-2,8-dioxo-4,6-diaza-1(4),9(4)-dipyridina-3(1,4),7(1,4)-dibenzenanonaphane-1,9-dicarboxamide |
| Uimh. CAS       | : 2438857-80-6                                                                                                                 |
| Cód an táirge   | : 202400607                                                                                                                    |

#### 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<br>Technical testing and analysis<br>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

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 |
|-------------------|-------------------|

### 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 atáirgeach, Catagóir 2                                   | H361 |
| Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 1              | H372 |
| Guaiseach don timpeallacht uisceach – Ghéarghuais, Catagóir H400<br>1 |      |
| 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. Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.

#### 2.2. Eilimintí lipéid

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

Hazard pictograms (CLP)



# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

|                                                                                              |                                                                                                                                                                                                                                                                                    |       |       |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|
|                                                                                              | GHS07                                                                                                                                                                                                                                                                              | GHS08 | GHS09 |
| Signal word (CLP)                                                                            | : Contúirt                                                                                                                                                                                                                                                                         |       |       |
| Hazard statements (CLP)                                                                      | : H302 - Díobhálach má shlogtar.<br>H361 - Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.<br>H372 - Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.<br>H410 - An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |       |       |
| Ráitis réamhchúraim (CLP)                                                                    | : P260 - Ná hanálaigh deannach.<br>P301+P312 - MÁ SHLOGTAR: Cuir glao ar IONAD NIMHE nó ar dhochtúir/lia má bhraitheann tú tinn.<br>P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn.                                                                                   |       |       |
| 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. Substaint

| Ainm                                                                                                                         | Sainaitheantóir táirge  |       | Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]                                                                 |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------|--------------------------------------------------------------------------------------------------------------------|
| 3,7-difluoro-N,N'-dimethyl-5-oxo-2,8-dioxa-4,6-diaza-1(4),9(4)-dipyridina-3(1,4),7(1,4)-dibenzenanonaphane-1,9-dicarboxamide | Uimh. CAS: 2438857-80-6 | ≤ 100 | Acute Tox. 4 (Bhéil), H302<br>Repr. 2, H361<br>STOT RE 1, H372<br>Aquatic Acute 1, H400<br>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 ionanálaithe                 | : 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

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

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

### 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 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.

#### 7.3. Úsáid shonrach deiridh nó úsáid sonracha deiridh

Níl aon fhaisméis bhreise ar fáil

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

### 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                                            | : Not available          |
| Boladh                                          | : Not available          |
| Tairseach bolaidh                               | : Not available          |
| Leáphointe                                      | : Not available          |
| 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                                 | : 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

Níl aon fhaisnéis bhreise ar fáil

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

### 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)                                | : Díobhálach má shlogtar.                                                                |
| Acute toxicity (dermal)                              | : 0                                                                                      |
| Acute toxicity (inhalation)                          | : 0                                                                                      |
| Creimeadh/greannú craicinn                           | : 0                                                                                      |
| Damáiste/greannú tromchúiseach súl                   | : 0                                                                                      |
| Íoghrú riospráide nó craicinn                        | : 0                                                                                      |
| Só-ghineacht ghaiméite                               | : 0                                                                                      |
| Carcanaigineacht                                     | : 0                                                                                      |
| Tocsaineacht atáirgthe                               | : Ceaptar go bhféadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. |
| Tocsaineacht sain-spriocorgáin (aon nochtadh amháin) | : 0                                                                                      |
| Tocsaineacht sain-spriocorgáin (ilnochtadh)          | : Déanann damáiste d'orgáin trí nochtadh fada nó ilnochtadh.                             |
| Guais asúite                                         | : 0                                                                                      |

#### 11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

### CUID 12: Faisnéis éiceolaíochta

#### 12.1. Tocsaineacht

|                                                                   |                                                                     |
|-------------------------------------------------------------------|---------------------------------------------------------------------|
| Guaiseach don chomhshaol uisceach,                                | : An-tocsaineach don saol uisceach.                                 |
| ghearrthéarmach (géarghuais)                                      |                                                                     |
| Guaiseach don chomhshaol uisceach, fadtéarmach (guais ainsealach) | : An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. |

#### 12.2. Inchoimeádachas agus díghrádaitheacht

|                                                                                                                                             |                        |
|---------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| 3,7-difluoro-N,N'-dimethyl-5-oxo-2,8-dioxa-4,6-diaza-1(4),9(4)-dipyridina-3(1,4),7(1,4)-dibenzenanonaphane-1,9-dicarboxamide (2438857-80-6) |                        |
| Inchoimeádachas agus díghrádaitheacht                                                                                                       | Not rapidly degradable |

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

### 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                                                          |                                                                                     |                                                                                       |
| Ní bhaineann le hábhar                                                              | Ní bhaineann le hábhar                                                              | Ní bhaineann le hábhar                                                                |
| Transport document description                                                      |                                                                                     |                                                                                       |
| UN 3077                                                                             | UN 3077 , MARINE POLLUTANT                                                          | UN 3077                                                                               |
| 14.3. Aicme nó aicmí guaise iompair                                                 |                                                                                     |                                                                                       |
| Ní bhaineann le hábhar                                                              | Ní bhaineann le hábhar                                                              | Ní bhaineann le hábhar                                                                |
|  |  |  |
| 14.4. Grúpa pacála                                                                  |                                                                                     |                                                                                       |
| Ní bhaineann le hábhar                                                              | Ní bhaineann le hábhar                                                              | Ní bhaineann le hábhar                                                                |
| 14.5. Guaiseacha comhshaoil                                                         |                                                                                     |                                                                                       |
| Contúirteach don chomhshaoil: Tá                                                    | Contúirteach don chomhshaoil: Tá<br>Truailleán mara: Tá                             | Contúirteach don chomhshaoil: Tá                                                      |

### 14.6. Réamhchúraimí speisialta don úsáideoir

#### Iompar ar talamh

Níl sonraí ar fáil.

#### Iompar ar muir

Níl sonraí ar fáil.

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

### Aeriompar

Níl sonraí ar fáil.

### 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

##### 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 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 Acute 1                     | Guaiseach don timpeallacht uisceach – Ghéarghuais, Catagóir 1                          |
| Aquatic Chronic 1                   | Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1                     |
| H302                                | Díobhálach 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.                             |
| H400                                | An-tocsaineach don saol uisceach.                                                      |
| H410                                | An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.                      |
| Repr. 2                             | Tocsaineach atáirgeach, Catagóir 2                                                     |
| STOT RE 1                           | Tocsaineach sain-spiocorgáin – Athnochtadh, Catagóir 1                                 |

Safety Data Sheet (SDS), EU

# Regorafenib impurity D

## Bileog Sonraí Sábháilteachta

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

---

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. 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 product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.