

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

#### 1.1. Sainaitheantóir táirge

Foirm an táirge	: Substance
Substance name	: Donepezil
Cód an táirge	: 201700357
Synonyms	: Donepezil, salts, hydrates, isomers and impurities where applicable

#### 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
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#### 1.3. Sonraí um sholáthraí na bileoige sonraí sábháilteachta

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#### 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]

Géarthocsaineacht (bhéil), Catagóir 2	H300
Damáiste tromchúiseach don tsúil/greannú súl, Catagóir 2	H319
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)



GHS06

Signal word (CLP)	: Contúirt
Hazard statements (CLP)	: H300 - Marfach má shlogtar. H319 - Ina chúis le greannú tromchúiseach don tsúil.
Ráitis réamhchúiraim (CLP)	: P264 - Nigh ... go láimhreach tar éis lámhsithe. 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 dhoctúir. P305+P351+P338 - I gCÁS TEAGMHÁLA LEIS NA SÚILE: Sruthlaítear go cúramach le huisce ar feadh roinnt nóiméad. Tóg amach na tadhall-lionsaí, más ann dóibh agus más

# Donepezil

## Bileog Sonraí Sábháilteachta

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

furasta é sin a dhéanamh. Lean den sruthlú.

P321 - Cóir liachta ar leith (féach threoir gharchabhrach forlíontach ar an lipéad seo).

P330 - Sruthlaítear an béal.

P337+P313 - Má mhaireann an greannú súile: Faigh comhairle/cúram liachta.

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

### 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]
Donepezil	-	≤ 100	Acute Tox. 2 (Bhéil), H300 (ATE=32.6 mg/kg meáchan coirp) Eye Irrit. 2, H319

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 ionanáilaithe	: Move to fresh air. Allow affected person to breathe fresh air.
Bearta garchabhrach tar éis teagmhála leis an gcráiceann	: 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.

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

Siomptóim/gortuithe tar éis ionanáilaithe	: Insufficient data available.
Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann	: Insufficient data available.
Siomptóim/gortuithe tar éis teagmhála leis an tsúil	: Insufficient data available.

### 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.

## CUID 5: Bearta comhrac dóiteáin

### 5.1. Meáin múchta

Meáin oiriúnacha um múchadh : Extinguishing blanket.

# Donepezil

## Bileog Sonraí Sábháilteachta

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

### 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

Níl aon fhaisnéis bhreise ar fáil

#### 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.

### 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.

Bearta sláinteachais : Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Coinníollacha stórála sábháilte, lena n-áirítear aon neamhlú

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: Rialúithe 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

# Donepezil

## Bileog Sonraí Sábháilteachta

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

### 8.1.5. Control banding

Níl aon fhaisnéis bhreise ar fáil

## 8.2. Rialuithe nochtá

### 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
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	: 5.4 – 6.6
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

# Donepezil

## Bileog Sonraí Sábháilteachta

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

### 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 dian-scaoilte 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)	: Marfach má shlogtar.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Donepezil	
LD50 ó bhéal francach	32.6 mg/kg
Creimeadh/greannú craicinn	: Not classified (Lack of data) pH: 5.4 – 6.6
Damáiste/greannú tromchúiseach súl	: Ina chúis le greannú tromchúiseach don tsúil. pH: 5.4 – 6.6
Íogru riospráide nó craicinn	: Not classified (Lack of data)
Só-ghineacht ghaiméite	: Not classified (Lack of data)
Carcanaigineacht	: Not classified (Lack of data)
Tocsaineacht atáirgthe	: Not classified (Lack of data)
Tocsaineacht sain-spriocorgáin (aon nochtadh amháin)	: Not classified (Lack of data)
Tocsaineacht sain-spriocorgáin (ilnochtadh)	: Not classified (Lack of data)
Guais asúite	: Not classified (Technical impossibility to obtain the data)

### 11.2. Information on other hazards

Níl aon fhaisnéis bhreise ar fáil

# Donepezil

## Bileog Sonraí Sábháilteachta

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

### 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 díghráiditheacht

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
<b>14.1. UN number or ID number</b>		
UN 2811	UN 2811	UN 2811
<b>14.2. Ainm seolta ceart UN</b>		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
<b>Transport document description</b>		
UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, II, (D/E)	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, II	UN 2811 Toxic solid, organic, n.o.s., 6.1, II
<b>14.3. Aicme nó aicmí guaise iompair</b>		
6.1	6.1	6.1

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## Bileog Sonraí Sábháilteachta

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

ADR	IMDG	IATA
		
<b>14.4. Grúpa pacála</b>		
II	II	II
<b>14.5. Guaiseacha comhshaoil</b>		
Contúirteach don chomhshaoil: No	Contúirteach don chomhshaoil: No Truailleán mara: No	Contúirteach don chomhshaoil: No

### 14.6. Réamhchúraimí speisialta don úsáideoir

#### Iompar ar talamh

Classification code (ADR)	: T2
Special provisions (ADR)	: 274, 614
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

#### Iompar ar muir

Special provision (IMDG)	: 274
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B21, B4
Tank instructions (IMDG)	: T3
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-A
Stowage category (IMDG)	: B
Properties and observations (IMDG)	: 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

# Donepezil

## Bileog Sonraí Sábhálteachta

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

CAO max net quantity (IATA) : 100kg  
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 sábhálteacht, 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 sábhálteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

## CUID 16: Faisnéis eile

Léiriú ar na hathruithe			
Cuid	Changed item	Change	Comments
	Dáta eisiúna	Modified	
	Reason for no classification	Added	
	Dáta athbhreithnithe	Added	
	Supersedes version of	Added	
2.1	Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]	Modified	
2.2	Hazard statements (CLP)	Modified	
2.2	Ráitis réamhchúraim (CLP)	Modified	



# Donepezil

## Bileog Sonraí Sábháilteachta

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

Léiriú ar na hathruithe			
Cuid	Changed item	Change	Comments
4.1	Bearta garchabhrach tar éis iontógála	Modified	
4.3	Other medical advice or treatment	Modified	
9.1	pH	Added	
9.1	Solubility in water	Modified	
11.1	Reason for no classification	Added	
11.1	LD50 ó bhéal francach	Modified	
11.1	ATE CLP (oral)	Modified	

Full text of H- and EUH-statements:	
Acute Tox. 2 (Bhéil)	Géarthocsaineacht (bhéil), Catagóir 2
Eye Irrit. 2	Damáiste tromchúiseach don tsúil/greannú súl, Catagóir 2
H300	Marfach má shlogtar.
H319	Ina chúis le greannú tromchúiseach don tsúil.

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.