

# Nomegestrol acetate for ID and assay

## Bileog Sonraí Sábháilteachta

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Dáta eisiúna: 03/04/2023 Dáta athbheithnithe: 22/10/2025 Supersedes version of: 03/04/2023 Leagan: 2.0

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

#### 1.1. Sainaitheantóir táirge

Foirm an táirge	: Substance
Substance name	: Nomegestrol acetate for ID and assay
Chemical name	: Nomegestrol acetate
Uimh. CE	: 261-379-8
Uimh. CAS	: 58652-20-3
Cód an táirge	: 201600644

#### 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
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#### 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
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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]

Suaiteoir inchríneach maidir leis an gcomhshaol, Catagóir 2	EUH431
Suaiteoir inchríneach maidir le sláinte an duine, Catagóir 1	EUH380
Carcanaigineacht, Catagóir 1A	H350
Tocsaineacht atáirgeach, Catagóir 1A	H360
Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 1	H372
Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1	H410 (M=10)

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

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

An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha. D'fhéadfadh sé a bheith ina chúis le hailse. D'fhéadfadh 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)



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	GHS08	GHS09
Signal word (CLP)	: Contúirt	
Hazard statements (CLP)	: EUH380 - D'fhéadfadh sé a bheith ina chúis le suaithheadh inchríneach sa duine. EUH431 - Ceaptar go bhfuil sé ina chúis le suaithheadh inchríneach sa chomhshaol. H350 - D'fhéadfadh sé a bheith ina chúis le hailse. H360 - D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn. H372 - Déanann damáiste d'orgáin (endocrine system) trí nochtadh fada nó ilnochtadh. H410 - An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.	
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. P263 - Seachain teagmháil le linn toirchis agus fad agus atá an chíos á tabhairt. 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. P280 - Caith lámhainní cosanta/éadaí cosanta/cosaint súile/cosaint aghaidhe. P314 - Faigh comhairle/cúram liachta má bhraitheann tú tinn. P391 - Bailigh doirteadh. 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)



GHS08

### 2.3. Guaiseacha eile

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is 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

Faisnéis eile

: Active substance (in pharmaceutical products).  
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]
Nomegestrol acetate substance identified as having endocrine disrupting properties	Uimh. CAS: 58652-20-3 Uimh. CE: 261-379-8	≤ 100	ED ENV 2, EUH431 ED HH 1, EUH380 Carc. 1A, H350 Repr. 1A, H360 STOT RE 1, H372 Aquatic Chronic 1, H410 (M=10)

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.

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Beartha 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.
Beartha 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.
Beartha 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.
Beartha 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. Faigh comhairle/cúram liachta láithreach.

### 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: Beartha 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.
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### 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: Beartha i gcás scaoileadh de thaisme

### 6.1. Réamhchúraimí pearsanta, trealamh cosanta agus nósanna imeachta éigeandála

Beartha ginearálta	: Avoid contact with skin, eyes and clothing.
<b>Do phearsanra neamh-éigeandála</b>	
Emergency procedures	: Evacuate unnecessary personnel.
<b>D'fhreagróirí éigeandála</b>	
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.

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### CUID 7: Láimhseáil agus stóráil

#### 7.1. Réamhchúraimí maidir le láimhseáil shábháilte

Additional hazards when processed	: Do not expose pregnant or breastfeeding women.
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 neamhlú

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

### 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	: White. almost white.
Dealramh	: Crystalline powder.
Molecular mass	: 370.49 g/mol
Boladh	: Not available
Tairseach bolaidh	: Not available
Leáphointe	: 176 – 181 °C
Reophointe	: Not available
Fiuchphointe	: Not available
Inadhainteacht	: Not available

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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)	: 3.7
Galbhúrú	: 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

## 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)	: ()
Acute toxicity (dermal)	: ()
Acute toxicity (inhalation)	: ()

#### Nomegestrol acetate (58652-20-3)

LD50 ó bhéal francach	> 2000 mg/kg (RTECS No RC8899200)
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Creimeadh/greannú craicinn	: ()
Damáiste/greannú tromchúiseach súl	: ()
Íoghrú riospráide nó craicinn	: ()
Só-ghineacht ghaiméite	: (Bunaithe ar shonraí atá ar fáil, ní chomhlíontar na critéir aicmithe.)
Carcanaigineacht	: D'fhéadfadh sé a bheith ina chúis le hailse.

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### Nomegestrol acetate (58652-20-3)

IARC group	2B - Possibly carcinogenic to humans
Tocsaineacht atáirgthe	: D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
Tocsaineacht sain-spríocorgáin (aon nochtadh amháin)	: ()
Tocsaineacht sain-spríocorgáin (ilnochtadh)	: Déanann damáiste d'orgáin (endocrine system) trí nochtadh fada nó ilnochtadh.
Guais asúite	: ()

### 11.2. Information on other hazards

#### Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

## CUID 12: Faisnéis éiceolaíochta

### 12.1. Tocsaineacht

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

### Nomegestrol acetate (58652-20-3)

EC50 72h - Algae [1]	3.07 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)
NOEC chronic fish	0.0013 mg/l (27 days, Danio rerio(zebra fish))
NOEC chronic crustacea	> 0.00365 mg/l (Daphnia magna (Water flea)) (OECD 211 method)
NOEC chronic algae	0.69 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)

### 12.2. Inchoimeádachas agus díghráiditheacht

### Nomegestrol acetate (58652-20-3)

Inchoimeádachas agus díghráiditheacht	Not rapidly degradable
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### 12.3. Acmhainneacht bhithbhailitheach

### Nomegestrol acetate (58652-20-3)

Partition coefficient n-octanol/water (Log Kow)	3.7
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### 12.4. Soghluaisteacht san ithir

Níl aon fhaisnéis bhreise ar fáil

### 12.5. Torthaí an mheasúnaithe PBT agus vPvB

### Nomegestrol acetate (58652-20-3)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system.

### 12.7. Éifeachtaí díobhálacha eile

Níl aon fhaisnéis bhreise ar fáil

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### 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
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077
<b>14.2. Ainm seolta ceart UN</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
<b>Transport document description</b>		
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
<b>14.3. Aicme nó aicmí guaise iompair</b>		
9	9	9
		
<b>14.4. Grúpa pacála</b>		
III	III	III
<b>14.5. Guaiseacha comhshaoil</b>		
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

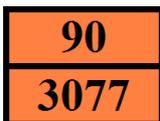
Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (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

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Hazard identification number (Kemler No.) : 90  
Orange plates :



Tunnel restriction code (ADR) : -

### Iompar ar muir

Special provision (IMDG) : 274, 335, 375, 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  
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

#### 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 (EU 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 (EC 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)

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### 15.2. Measúnú sábhálteachta ceimicí

Níl aon fhaisnéis bhreise ar fáil

#### CUID 16: Faisnéis eile

##### Léiriú ar na hathruithe

Cuid	Changed item	Comments
	(ADR) (RID)	Added
	Number of blue cones/lights (ADN)	Added
	Equipment required (ADN)	Added
	Carriage permitted (ADN)	Added
	Excepted quantities (ADN)	Added
	Limited quantities (ADN)	Added
	Danger labels (ADN)	Added
	Classification code (ADN)	Added
	Proper Shipping Name (RID)	Added
	Hazard identification number (RID)	Added
	Colis express (express parcels) (RID)	Added
	Special provisions for carriage - Loading, unloading and handling (RID)	Added
	Special provisions for carriage – Bulk (RID)	Added
	Special provisions for carriage – Packages (RID)	Added
	Transport category (RID)	Added
	Tank codes for RID tanks (RID)	Added
	Portable tank and bulk container special provisions (RID)	Added
	Portable tank and bulk container instructions (RID)	Added
	Mixed packing provisions (RID)	Added
	Packing provisions (RID)	Added
	Packing instructions (RID)	Added
	Excepted quantities (RID)	Added
	Limited quantities (RID)	Added
	Special provisions (RID)	Added
	Packing group (RID)	Added
	Classification code (RID)	Added
	ERG code (IATA)	Added
	Special provisions (IATA)	Added
	CAO max net quantity (IATA)	Added
	CAO packing instructions (IATA)	Added
	PCA max net quantity (IATA)	Added

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Léiriú ar na hathruithe		
Cuid	Changed item	Comments
	PCA packing instructions (IATA)	Added
	PCA limited quantity max net quantity (IATA)	Added
	PCA Limited quantities (IATA)	Added
	PCA Excepted quantities (IATA)	Added
	Danger labels (IATA)	Added
	Proper Shipping Name (IATA)	Added
	Proper Shipping Name (IMDG)	Added
	Danger labels (IMDG)	Added
	EmS-No. (Spillage)	Added
	EmS-No. (Fire)	Added
	Limited quantities (IMDG)	Added
	Stowage and handling (IMDG)	Added
	Stowage category (IMDG)	Added
	Tank special provisions (IMDG)	Added
	Tank instructions (IMDG)	Added
	IBC special provisions (IMDG)	Added
	IBC packing instructions (IMDG)	Added
	Excepted quantities (IMDG)	Added
	Special provision (IMDG)	Added
	Special provisions for carriage - Loading, unloading and handling (ADR)	Added
	Special provisions for carriage - Bulk (ADR)	Added
	Special provisions for carriage - Packages (ADR)	Added
	Tank code (ADR)	Added
	Portable tank and bulk container special provisions (ADR)	Added
	Portable tank and bulk container instructions (ADR)	Added
	Mixed packing provisions (ADR)	Added
	Packing provisions (ADR)	Added
	Packing instructions (ADR)	Added
	Vehicle for tank carriage	Added
	Adverse health effects caused by endocrine disrupting properties	Added
	Supersedes version of	Added
	Dáta athbhreithnithe	Added
1.1	Uimh. CAS	Added
1.1	Uimh. CE	Added
1.1	Synonyms	Removed

# Nomegestrol acetate for ID and assay

## Bileog Sonraí Sábháilteachta

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

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
1.1	Ainm	Modified
1.2	Restrictions on use	Modified
1.2	Úsáid na substainte / an mheascáin	Modified
1.2	Príomhchatagóir úsáide	Removed
2.1	Éifeachtaí díobhálacha fisiciceimiceacha, um shláinte an duine agus um an comhshaol	Modified
2.1	Aicme de réir Rialachán (CE) Uimh. 1272/2008 [CLP]	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.2	Ráitis réamhchúraim (CLP)	Modified
2.3	Faisnéis eile	Added
4.1	First-aid measures general	Added
4.1	Beartha garchabhrach tar éis teagmhála leis an gcráiceann	Modified
4.1	Beartha garchabhrach tar éis ionanáilaithe	Modified
4.1	Beartha garchabhrach tar éis iontógála	Modified
4.1	Beartha garchabhrach tar éis teagmhála leis an tsúil	Modified
4.2	Symptoms/effects	Removed
4.2	Siomptóim/gortuithe tar éis iontógála	Removed
4.2	Siomptóim/gortuithe tar éis teagmhála leis an gcráiceann	Removed
4.2	Siomptóim/gortuithe tar éis ionanáilaithe	Removed
4.2	Siomptóim/gortuithe tar éis teagmhála leis an tsúil	Removed
4.3	Other medical advice or treatment	Removed
5.1	Meáin mhí-oiriúnacha um múchadh	Added
5.1	Meáin oiriúnacha um múchadh	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Guais dóiteáin	Removed
5.3	Cosaint i rith comhrac dóiteáin	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.1	Beartha ginearálta	Modified
6.2	Réamhchúraimí comhshaoil	Added
6.3	I gcomhair srianta	Added
6.3	Modhanna um ghlanadh	Modified

# Nomegestrol acetate for ID and assay

## Bileog Sonraí Sábháilteachta

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

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Modified
7.1	Réamhchúraimí maidir le láimhseáil shábháilte	Modified
7.1	Bearta sláinteachais	Modified
7.2	Coinníollacha stórála	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.3	Specific end uses	Removed
8.2	Cosaint riospráide	Modified
8.2	Cosaint lámha	Modified
8.2	Cosaint súl	Modified
8.2	Rialuithe iomchuí innealtóireachta	Modified
8.2	Cosaint chraicinn agus choirp	Modified
9	Partition coefficient n-octanol/water (Log Kow)	Added
9	Molecular mass	Added
9	Leáphointe	Added
9	Dath	Added
9	Dealramh	Modified
9	Boladh	Removed
10.1	Imoibríocht	Removed
10.5	Ábhair neamh-chomhoiriúnacha	Removed
10.6	Táirgí dianscaoilte guaiseacha	Removed
11.1	IARC group	Added
11.1	LD50 ó bhéal francach	Modified
12.1	NOEC chronic fish	Added
12.1	NOEC chronic crustacea	Added
12.1	NOEC chronic algae	Added
12.1	EC50 72h - Algae [1]	Added
12.1	Éiceolaíocht - ginearálta	Removed
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added
13.1	Regional waste regulation	Removed
14.1	(ADR) (ADN)	Added
14.1	(ADR) (IMDG)	Added
14.1	(ADR) (IATA)	Added
14.1	(ADR) (ADR)	Added
14.2	Proper Shipping Name (ADN)	Added
14.2	Proper Shipping Name (ADR)	Added

# Nomegestrol acetate for ID and assay

## Bileog Sonraí Sábháilteachta

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

Léiriú ar na hathruithe		
Cuid	Changed item	Comments
14.3	Danger labels (RID)	Added
14.3	Danger labels (ADR)	Added
14.3	Class (ADR)	Added
14.4	Packing group (ADN)	Added
14.4	Packing group (IATA)	Added
14.4	Packing group (IMDG)	Added
14.4	Packing group (ADR)	Added
14.6	Additional requirements/Remarks (ADN)	Added
14.6	Special provisions (ADN)	Added
14.6	Packing provisions (IMDG)	Added
14.6	Packing instructions (IMDG)	Added
14.6	Transport category (ADR)	Added
14.6	Special provisions (ADR)	Added
14.6	Excepted quantities (ADR)	Added
14.6	Limited quantities (ADR)	Added
14.6	Tunnel restriction code (ADR)	Added
14.6	Hazard identification number (Kemler No.)	Added
14.6	Classification code (ADR)	Added

Full text of H- and EUH-statements:	
Aquatic Chronic 1	Guaiseach don timpeallacht uisceach – Guais Ainsealach, Catagóir 1
Carc. 1A	Carcanaigineacht, Catagóir 1A
ED ENV 2	Suaiteoir inchríneach maidir leis an gcomhshaol, Catagóir 2
ED HH 1	Suaiteoir inchríneach maidir le sláinte an duine, Catagóir 1
EUH380	D'fhéadfadh sé a bheith ina chúis le suaitheadh inchríneach sa duine.
EUH431	Ceaptar go bhfuil sé ina chúis le suaitheadh inchríneach sa chomhshaol.
H350	D'fhéadfadh sé a bheith ina chúis le hailse.
H360	D'fhéadfadh sé damáiste a dhéanamh do thorthúlacht nó don leanbh sa bhroinn.
H372	Déanann damáiste d'orgáin (endocrine system) trí nochtadh fada nó ilnochtadh.
H410	An-tocsaineach don saol uisceach, le héifeachtaí fadtréimhseacha.
Repr. 1A	Tocsaineacht atáirgeach, Catagóir 1A
STOT RE 1	Tocsaineacht sain-spríocorgáin – Athnochtadh, Catagóir 1

Safety Data Sheet (SDS), EU

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