

Gonadorelin Formulation

Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.0	28.09.2024	641764-00020	Date of first issue: 27.04.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier		
	Trade name	:	Gonadorelin Formulation
	Other means of identification	:	FERTAGYL SYNTHETIC GONADOTROPHIN RELEASING HORMONE (37210)
1.2	Relevant identified uses of th	e s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1
Reproductive toxicity, Category 2

Specific target organ toxicity - repeated exposure, Category 1

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



H317: May cause an allergic skin reaction.H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.H372: Causes damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024	-	DS Number: 41764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
Signa	Signal word		Danger	
Hazard statements		:	H317 H361fd H372	May cause an allergic skin reaction. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure.
Preca	Precautionary statements		Prevention P201	: Obtain special instructions before use.
			P264 P270	Wash skin thoroughly after handling. Do not eat, drink or smoke when using this prod- uct.
			P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
			Response:	
			P308 + P31	3 IF exposed or concerned: Get medical advice/ attention.
			P333 + P31	3 If skin irritation or rash occurs: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Benzyl alcohol Gonadorelin

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Benzyl alcohol	100-51-6	Acute Tox. 4; H302	>= 1 - < 10
	202-859-9	Eye Irrit. 2; H319	
	603-057-00-5	Skin Sens. 1B; H317	



according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024		
6.0	28.09.2024	641764-00020	Date of first issue: 27.04.2016		
	dorelin	34973-08-5	Acute toxicity esti- mate Acute oral toxicity: 1,200 mg/kg Repr. 2; H361fd STOT RE 1; H372 (Endocrine system) specific concentration limit Repr. 2; H361fd >= 0.001 % STOT RE 1; H372 >= 0.001 %	>= 0.001 - < 0.1	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks	:	May cause an allergic skin reaction.
I		Suspected of damaging fertility. Suspected of damaging the



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024	-	9S Number: 1764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
			unborn child. Causes damag exposure.	e to organs through prolonged or repeated
	cation of any immediate	meo :		nd special treatment needed atically and supportively.
SECTI	ON 5: Firefighting meas	sur	es	
5.1 Exti	inguishing media			
Su	itable extinguishing media	:	Water spray Alcohol-resistar Carbon dioxide Dry chemical	
	suitable extinguishing dia	:	None known.	
5.2 Spe	cial hazards arising from	the	substance or r	nixture
	ecific hazards during fire- nting	:	Exposure to co	mbustion products may be a hazard to health.
Ha uct	zardous combustion prod- s	:	Carbon oxides	
5.3 Adv	vice for firefighters			
	ecial protective equipment firefighters	:		fire, wear self-contained breathing apparatus. rotective equipment.
	Specific extinguishing meth- ods : Use extinguishing measures that are appropriate to loc cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is sa so. Evacuate area.		d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to de	

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions	

Environmental precautions		Avoid release to the environment.
		Prevent further leakage or spillage if safe to do so.
		Prevent spreading over a wide area (e.g. by containment or oil
		barriers).



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024	SDS Number: 641764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
		•	se of contaminated wash water. should be advised if significant spillages ned.
6.3 Method	Is and material for co	ntainment and clean	ing up
Methods for cleaning up :		For large spills, p ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	rt absorbent material. provide dyking or other appropriate contain- terial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. 15 of this SDS provide information regarding ational requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
:	Use only with adequate ventilation.
:	Do not get on skin or clothing.
	Do not breathe mist or vapours.
	Do not swallow.
	Avoid contact with eyes.
	Wash skin thoroughly after handling.
	Handle in accordance with good industrial hygiene and safety
	practice, based on the results of the workplace exposure as- sessment
	Do not eat, drink or smoke when using this product.
	Take care to prevent spills, waste and minimize release to the environment.
:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.
	:

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024	SDS Number: 641764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
		Organic peroxide Explosives Gases	25
-	c end use(s) c use(s)	: No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
Gonadorelin	34973-08-5	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 µg/100 cm²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic	22 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024	SDS Number: 641764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016		
		Soil	0.456 mg/kg		
8.2 Expos	sure controls				
Engi	neering measures				
	re adequate ventilatior nize workplace exposu				
Pers	onal protective equip	ment			
Eye/f	Eye/face protection : Wear the following personal protective equipment: Safety glasses Equipment should conform to I.S. EN 166				
Hand	l protection	Equipmont			
М	aterial	: Chemical-r	esistant gloves		
R	emarks	on the cond stance and determined applications chemicals	: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.		
Skin	and body protection	: Select appl resistance potential. Skin contac	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure		
Resp	iratory protection	: If adequate sure asses ommended	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387		
Fi	lter type		pour type (A)		

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ver 6.0	sion	Revision Date: 28.09.2024		S Number: 764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Flash p	point	:	No data available	2
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscosi Visc	ty cosity, dynamic	:	No data available	9
	Visc	cosity, kinematic	:	No data available	9
	Solubili Wat	ity(ies) ter solubility	:	No data available	
	Partitio octanol	n coefficient: n- I/water	:	No data available	9
	Vapour	pressure	:	No data available	9
	Density	/	:	No data available	9
	Relative	e vapour density	:	No data available	9
		e characteristics ticle size	:	No data available	
9.2		nformation			
	Explosi		:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available	9
	Molecu	ılar weight	:	Not applicable	



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024	SDS Number: 641764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
SECTION	N 10: Stability and	reactivity	
10.1 Read	ctivity		
Not c	lassified as a reactivit	y hazard.	
10.2 Cher	nical stability		
Stabl	e under normal condi	tions.	
10.3 Poss	sibility of hazardous	reactions	
Haza	rdous reactions	: Can react with	n strong oxidizing agents.
10.4 Cond	ditions to avoid		
Cond	litions to avoid	: None known.	
10.5 Inco	mpatible materials		
Mate	rials to avoid	: Oxidizing age	nts

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	of :	Inhalation Skin contact Ingestion Eye contact
Acute toxicity		
Not classified based on avai	lable	information.
Product:		
Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Components:		
Benzyl alcohol:		
Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist

Gonadorelin:

tion toxicity

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Revision Date: 28.09.2024			Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
oral toxicity	:	LD50 (Rat): > 3	,000 mg/kg
		LD50 (Mouse):	> 4,000 mg/kg
inhalation toxicity	:	Remarks: No da	ata available
dermal toxicity	:	Remarks: No da	ata available
		<i>.</i>	
	ailable i	nformation.	
		5.1.1	
	-		deline 404
	:		
dorelin:			
rks	:	No data availab	le
es d	:	OECD Test Gui	deline 405 s, reversing within 21 days
dorelin:			
	:	No data availab	le
ratory or skin sensi	tisatio	n	
	reactio	n.	
•		nformation.	
vl alcohol:			
	:		nsult patch test (HRIPT)
	:	Skin contact Humans	
20			
es :	:	positive	
	28.09.2024 oral toxicity inhalation toxicity dermal toxicity corrosion/irritation assified based on avain onents: /l alcohol: es ad t dorelin: rks us eye damage/eye assified based on avain onents: /l alcohol: es ad t dorelin: rks ratory or skin sensi sensitisation ause an allergic skin ratory sensitisation ause an allergic skin ratory sensitisation assified based on avain onents: /l alcohol: es ad t	28.09.2024 641 oral toxicity : inhalation toxicity : inhalation toxicity : dermal toxicity : corrosion/irritation : assified based on available i : conents: // alcohol: vl : dorelin: : rks : // alcohol: : assified based on available i : conents: : // alcohol: : es : id : conents: : // alcohol: : es : id : ratory or skin sensitisation : ause an allergic skin reactio : ratory sensitisation : ause an allergic skin reactio : id : <t< td=""><td>28.09.2024 641764-00020 oral toxicity : LD50 (Rat): > 3 LD50 (Mouse): inhalation toxicity : Remarks: No data dermal toxicity inhalation toxicity : Remarks: No data available information. corrosion/irritation : Remarks: No data available information. corrosion/irritation : Remarks: No data available information. connents: // alcohol: : via according to the second on available information. : dorelin: : No data available rks : No data available us eye damage/eye irritation : : assified based on available information. : : onents: // alcohol: : : via according to the second on available information. : : officient to the second on available information. : : ratory or skin sensitisation : : : ause an allergic skin reaction. : : : ratory sensitisation : : : aussified based on available information. :</td></t<>	28.09.2024 641764-00020 oral toxicity : LD50 (Rat): > 3 LD50 (Mouse): inhalation toxicity : Remarks: No data dermal toxicity inhalation toxicity : Remarks: No data available information. corrosion/irritation : Remarks: No data available information. corrosion/irritation : Remarks: No data available information. connents: // alcohol: : via according to the second on available information. : dorelin: : No data available rks : No data available us eye damage/eye irritation : : assified based on available information. : : onents: // alcohol: : : via according to the second on available information. : : officient to the second on available information. : : ratory or skin sensitisation : : : ause an allergic skin reaction. : : : ratory sensitisation : : : aussified based on available information. :

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Version 6.0	Revision Date: 28.09.2024	-	DS Number: 1764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
II			rate in humans	
Gona Rema	dorelin: arks	:	No data available	
	cell mutagenicity assified based on availa	able	information.	
Com	oonents:			
Benz	yl alcohol:			
Geno	toxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
Geno	toxicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo /) :: Intraperitoneal injection
Gona	dorelin:			
Geno	toxicity in vitro	:	Result: negative	rial reverse mutation assay (AMES) on data from similar materials
			Result: negative	o mammalian cell gene mutation test on data from similar materials
			Result: negative	nosome aberration test in vitro on data from similar materials
Germ sessn	cell mutagenicity- As- nent	:	Weight of evidend cell mutagen.	ce does not support classification as a germ
Carci	nogenicity			
Not c	assified based on availa	able	information.	
<u>Com</u>	oonents:			
	yl alcohol:			
	cation Route sure time od	:	Mouse Ingestion 103 weeks OECD Test Guide negative	eline 451
Gona	dorelin:			
Speci		:	Mouse	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Gonadorelin Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
6.0		641764-00020	Date of first issue: 27.04.2016
LOAE Result Rema	rks es ure time L	 Rat 1 Years 0.05 mg/kg b negative Benign tumo The mechan mans. 	ta from similar materials body weight

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Benzyl alcohol:	
Effects on fertility	 Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal develop- ment	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative
Gonadorelin:	
Effects on fertility	 Test Type: Fertility/early embryonic development Species: Rat, female Application Route: Subcutaneous Fertility: LOAEL: 50 μg/kg Result: Effects on fertility Remarks: Based on data from similar materials Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Subcutaneous Fertility: LOAEL: 500 μg/kg Result: Effects on fertility Remarks: Based on data from similar materials Test Type: Fertility/early embryonic development Species: Rabbit Test Type: Fertility/early embryonic development Species: Rabbit Application Route: Subcutaneous Fertility: LOAEL: 1,000 μg/kg Result: Effects on fertility

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Version 6.0	Revision Date: 28.09.2024		OS Number: 1764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
			Test Type: Fertili Species: Dog, ma Application Route Fertility: LOAEL: Result: Effects or	e: Subcutaneous 107 - 214 μg/kg
Effeo men	cts on foetal develop- t	:	Species: Rat Application Route Developmental T	yo-foetal development e: Subcutaneous oxicity: LOAEL: >= 2 μg/kg n foetal development
			Species: Rabbit Application Route Developmental T	/o-foetal development e: Subcutaneous oxicity: LOAEL: > 20 μg/kg n foetal development
	oductive toxicity - As- ment	:	fertility, based on	f adverse effects on sexual function and animal experiments., Some evidence of n development, based on animal experi-
	T - single exposure			
	classified based on avail T - repeated exposure	able	information.	
	ses damage to organs th	roug	h prolonged or rep	peated exposure.
	ponents:			
Targ	adorelin: et Organs essment	:	Endocrine syster Causes damage exposure.	n to organs through prolonged or repeated
Rep	eated dose toxicity			
<u>Com</u>	ponents:			
Ben	zyl alcohol:			
Spec NOA Appl Expo Meth	EL ication Route osure time		Rat 1.072 mg/l inhalation (dust/n 28 Days OECD Test Guid	
	adorelin:			
		:	Rat 0.12 mg/kg Intramuscular 15 Days	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024		DS Number: 1764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
Remarks		:	No significant ac	lverse effects were reported
Speci NOAE Applio Expos Rema	EL cation Route sure time		Rat 0.072 mg/kg Intravenous 15 Days No significant ac	lverse effects were reported
Speci NOAE Applio Expos Rema	EL cation Route sure time		Dog 0.12 mg/kg Intramuscular 15 Days No significant ac	lverse effects were reported
Speci NOAE Applic Expos Rema	EL cation Route sure time		Dog 0.072 mg/kg Intravenous 15 Days No significant ac	lverse effects were reported

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

:

Components:

Gonadorelin:

Ingestion

Symptoms: Nausea, Abdominal pain, Headache, Palpitation, acne, liver function change, bronchospasm, anaphylaxis

SECTION 12: Ecological information

12.1 Toxicity

Components:

Benzyl alcohol:

Toxicity to fish

: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h



Gonadorelin Formulation

Version 6.0	Revision Date: 28.09.2024		DS Number: 1764-00020	Date of last issue: 06.04.2024 Date of first issue: 27.04.2016
	ty to daphnia and other ic invertebrates	:	Exposure time: 4	nagna (Water flea)): 230 mg/l 8 h ⁻ est Guideline 202
	Toxicity to algae/aquatic : plants		mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 770 2 h Fest Guideline 201
			mg/l Exposure time: 7	irchneriella subcapitata (green algae)): 310 2 h ⁻ est Guideline 201
	ty to daphnia and other ic invertebrates (Chron- city)		Exposure time: 2 Species: Daphnia	1 d a magna (Water flea) ⁻ est Guideline 211

12.2 Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability	: Result: Readily biodegradable.
	Biodegradation: 92 - 96 %
Biodegradability	Exposure time: 14 d

12.3 Bioaccumulative potential

Components:

Benzyl alcohol:		
Partition coefficient: n-	:	log Pow: 1.05
octanol/water		

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment	: This substance/mixture contains no components considered
	to be either persistent, bioaccumulative and toxic (PBT), or
	very persistent and very bioaccumulative (vPvB) at levels of
	0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components consid-
		ered to have endocrine disrupting properties according to
		REACH Article 57(f) or Commission Delegated regulation



Gonadorelin Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
6.0		641764-00020	Date of first issue: 27.04.2016

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
11 1 Dealing group		

14.4 Packing group



Gonadorelin Formulation

	Version	Revision Date:	SDS	S Number:	Date of last issue: 06.04.2024		
	6.0	28.09.2024	641	764-00020	Date of first issue: 27.04.2016		
	ADN		:	Not regulated as a	a dangerous good		
	ADR		:	Not regulated as a	a dangerous good		
	RID		:	: Not regulated as a dangerous good			
	IMDG		:	Not regulated as a	a dangerous good		
	IATA (Cargo)	:	Not regulated as a	a dangerous good		
	IATA (Passenger)	:	Not regulated as a	a dangerous good		
14.5 Environmental hazards							
Not regulated as a dangerous good							
	14.6 Special precautions for user						

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3 Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.
		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
REACH - Candidate List of Substances of Very High	:	Not applicable
Concern for Authorisation (Article 59). Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation	:	Not applicable



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.0	28.09.2024	641764-00020	Date of first issue: 27.04.2016

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION	16:	Other	information
---------	-----	-------	-------------

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H302	:	Harmful if swallowed.
H317	:	May cause an allergic skin reaction.
H319	:	Causes serious eye irritation.
H361fd	:	Suspected of damaging fertility. Suspected of damaging the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
Full text of other abbreviation	ns	
Acute Tox.	:	Acute toxicity
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.0	28.09.2024	641764-00020	Date of first issue: 27.04.2016

cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data		eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

Classification of the	e mixture:	Classification procedure:
Skin Sens. 1	H317	Calculation method
Repr. 2	H361fd	Calculation method
STOT RE 1	H372	Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN