

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

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

1.1 Product identifier Trade name	:	Recombinant Bovine Somatotropin Formulation
1.2 Relevant identified uses of	the s	substance 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	e 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)

Eye irritation, Category 2 Long-term (chronic) aquatic hazard, Category 3 H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)				
Hazard pictograms	:			
		$\mathbf{\dot{\mathbf{v}}}$		
Signal word	:	Warning		
Hazard statements	:	H319	Causes serious eye irritation.	



Version 1.19	Revision Date: 06.04.2024	SDS Number: 413063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
		H412	Harmful to aquatic life with long lasting effects.
Preca	utionary statements	: Prevention:	:
		P264	Wash skin thoroughly after handling.
		P273	Avoid release to the environment.
		P280	Wear eye protection/ face protection.
		Response:	
		P337 + P31	3 If eye irritation persists: Get medical advice/ attention.

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. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Recombinant Bovine Somatotro- pin	Not Assigned		>= 20 - < 30
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity esti- mate Acute oral toxicity: 1,620 mg/kg	>= 10 - < 20
Benzyl benzoate	120-51-4 204-402-9 607-085-00-9	Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 2;	>= 10 - < 20

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



Recombinant Bovine Somatotropin Formulation

ersion	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015
			H411 M-Factor (Acute aquatic toxicity): 1 Acute toxicity esti- mate Acute oral toxicity: 1,700 mg/kg

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 if symptoms occur.
	In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
	In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
	If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
4.2	Most important symptoms an	d e	ffects, both acute and delayed
	Risks	:	Causes serious eye irritation.
4.3	Indication of any immediate n	ned	lical attention and special treatment needed
	Treatment	:	Treat symptomatically and supportively.



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Created because arising from	46.0	aubatanaa ar mixtura

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

Commission Regulation (EU) 2020/878

Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015
		ment to keep n be pumped, st Clean up rema bent. Local or nation posal of this m employed in th mine which reg Sections 13 an	e, provide dyking or other appropriate contain- naterial from spreading. If dyked material can ore recovered material in appropriate container. and regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- gulations are applicable. In 15 of this SDS provide information regarding r national 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

Technical measures	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling	Use only with adequate ventilation. Avoid inhalation of vapour or mist. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. 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 Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	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. Wash contami- nated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Gases

7.3 Specific end use(s)



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Recombinant Bo- vine Somatotropin	Not As- signed	TWA	OEB 3 (>= 10 < 100 μg/m3)	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 benzoate	Workers	Inhalation	Long-term systemic effects	5.1 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	102 mg/m3
	Workers	Skin contact	Long-term systemic effects	2.6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.25 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	25 mg/m3
	Consumers	Skin contact	Long-term systemic effects	1.3 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	78 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	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	4 mg/kg

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

Recombinant Bovine Somatotropin Formulation

Version 1.19	Revision Date: 06.04.2024	SDS Number: 413063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015	
				-

		effects	bw/day
Consumers	Ingestion	Acute systemic ef-	20 mg/kg
		fects	bw/day

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

h		
Substance name	Environmental Compartment	Value
Benzyl benzoate	Fresh water	0.017 mg/l
	Marine water	0.002 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	10.66 mg/kg dry weight (d.w.)
	Marine sediment	1.07 mg/kg dry weight (d.w.)
	Soil	2.12 mg/kg dry weight (d.w.)
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
	Soil	0.456 mg/kg

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection :		Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially



Version 1.19	Revision Date: 06.04.2024	SDS Number: 413063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
Respi	ratory protection	sure assessm ommended g	clothing. Incal exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- uidelines, use respiratory protection. Inould conform to I.S. EN 14387
Fil	ter type		rticulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	opaque, yellow
Odour	:	musty
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
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	No data available

Commission Regulation (EU) 2020/878



Recombinant Bovine Somatotropin Formulation

Versior 1.19	Revision Date: 06.04.2024	SDS Number: 413063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015	
	ntition coefficient: n- tanol/water	: No data availal	ble	
Va	pour pressure	: No data availal	ble	
Re	elative density	: No data availal	ble	
De	ensity	: No data availal	ble	
Re	elative vapour density	: No data availal	ble	
Pa	rticle characteristics Particle size	: No data availal	ble	
9.2 Otł	er information			
E>	plosives	: Not explosive		
O	idizing properties	: The substance	or mixture is not classified as oxidizing.	
E١	aporation rate	: No data availal	ble	
M	blecular weight	: No data availal	ble	

SECTION 10: Stability and reactivity

10.1 Reactivity Not classified as a reactivity haze	aro	J.
10.2 Chemical stability Stable under normal conditions.		
10.3 Possibility of hazardous react	io	ns
Hazardous reactions :	:	Can react with strong oxidizing agents.
10.4 Conditions to avoid		
Conditions to avoid :	:	None known.
10.5 Incompatible materials		
Materials to avoid :	:	Oxidizing agents
10.6 Hazardous decomposition pro No hazardous decomposition pro		

SECTION 11: Toxicological information

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



rsion 9	Revision Date: 06.04.2024		S Number: 3063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
Information on likely routes of exposure		:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity			
	lassified based on availa	ble	information.	
Prod			A	
Acute	e oral toxicity	:	Method: Calculation	mate: > 2,000 mg/kg on method
Acute inhalation toxicity		:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method	
<u>Com</u>	oonents:			
Reco	mbinant Bovine Somat	otro	opin:	
Acute	inhalation toxicity	:	LC50 (Rat): 30,00 Exposure time: 1 Test atmosphere:	h
Benz	yl alcohol:			
Acute	e oral toxicity	:	LD50 (Rat): 1,620) mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 4.1 Exposure time: 4 Test atmosphere: Method: OECD Te	h dust/mist
Benz	yl benzoate:			
	e oral toxicity	:	LD50 (Rat): 1,700	mg/kg
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
	corrosion/irritation lassified based on availa	ble	information.	
Com	ponents:			
Reco	mbinant Bovine Somat	otro	opin:	
Speci		:	Rabbit	
Rema	arks	:	slight irritation	
Benz	yl alcohol:			
Speci		:	Rabbit	r 404
Metho	bd	:	OECD Test Guide	eline 404



rsion 9	Revision Date: 06.04.2024	SDS Number: 413063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
Resu	t	: No skin irrita	tion
Benz	yl benzoate:		
Speci	es	: Rabbit	
Metho	bd		Guideline 404
Resu	t	: No skin irrita	tion
Serio	us eye damage/eye i	rritation	
Caus	es serious eye irritation	n.	
Com	oonents:		
Reco	mbinant Bovine Som	atotropin:	
Speci		: Rabbit	
Rema	arks	: slight irritatio	n
Benz	yl alcohol:		
Speci		: Rabbit	
Metho			Guideline 405
Resu	t	: Irritation to e	yes, reversing within 21 days
Benz	yl benzoate:		
Speci	es	: Rabbit	
Resu	t	: No eye irritat	ion
Resp	iratory or skin sensit	isation	
Skin	sensitisation		
	assified based on ava	ilable information.	
	iratory sensitisation		
Not c	assified based on ava	ilable information.	
<u>Com</u>	oonents:		
	yl alcohol: -	•• • • •	
Test		: Maximisation	
Expo: Speci	sure routes	: Skin contact : Guinea pig	
Metho			Guideline 406
Resu		: negative	
Benz	yl benzoate:		
Test		· I ocal lymph	node assay (LLNA)
	sure routes	: Skin contact	
Expos			
Expos Speci		: Mouse	
	es od		Guideline 429



ersion 19	Revision Date: 06.04.2024	SDS Number: 413063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
	cell mutagenicity assified based on av	ailable information.	
<u>Comp</u>	onents:		
Benzy	vl alcohol:		
Genot	oxicity in vitro	: Test Type: I Result: nega	Bacterial reverse mutation assay (AMES) ative
Genot	oxicity in vivo	cytogenetic Species: Mo	buse Route: Intraperitoneal injection
Benzy	l benzoate:		
Genot	oxicity in vitro	: Test Type: I Result: nega	Bacterial reverse mutation assay (AMES) ative
		Result: posi	n vitro mammalian cell gene mutation test tive ased on data from similar materials
		Result: nega	Chromosome aberration test in vitro ative ased on data from similar materials
Genotoxicity in vivo		mammalian Species: Ra Application Result: nega	Route: Ingestion

Components:

Benzyl alcohol:

Species	Mouse
Application Route	Ingestion
Exposure time	103 weeks
Method	OECD Test Guideline 451
Result	negative

Reproductive toxicity

Not classified based on available information.



Version 1.19	Revision Date: 06.04.2024		umber: 3-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015	
Con	nponents:				
	zyl alcohol: cts on fertility	Sp Ap Re	ecies: Rat plication Rou sult: negativ	ility/early embryonic development ute: Ingestion e ed on data from similar materials	
Effe men	cts on foetal develop- t	Sp Ap	ecies: Mous	ute: Ingestion	
	zyl benzoate: cts on foetal develop- it	Sp Ap	ecies: Rat	oryo-foetal development ute: Ingestion e	
Not STC Not Rep	OT - single exposure classified based on avail OT - repeated exposure classified based on avail eated dose toxicity mponents:				
	ombinant Bovine Som	atotronir			
Spe Exp		: Ra : 90	t d	dverse effects were reported	
Spe NO/ App	AEL lication Route osure time	: inh : 28	t 72 mg/l alation (dust Days CD Test Gu		
Spe NO/ App		: Ski	t 1 mg/kg n contact Veeks		



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

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.

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
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
Benzyl benzoate:		
Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 2.32 mg/l Exposure time: 96 h Method: Regulation (EC) No. 440/2008, Annex, C.1
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3.09 mg/l Exposure time: 48 h



Vers 1.19		Revision Date: 06.04.2024		0S Number: 3063-00020	Date of last issue: 30.09.2023 Date of first issue: 11.12.2015
				Method: OECD T	est Guideline 202
	Toxicity plants	/ to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD T	
				NOEC (Pseudoki mg/l Exposure time: 72 Method: OECD T	
	M-Fact icity)	or (Acute aquatic tox-	:	1	
	Toxicity	<i>i</i> to microorganisms	:	EC50 : > 10,000 r Exposure time: 3 Method: ISO 8192	h
		v to daphnia and other invertebrates (Chron- ity)	:	NOEC: 0.258 mg, Exposure time: 2' Species: Daphnia Method: OECD T	l d magna (Water flea)
12.2	Persis	tence and degradabil	ity		
	Compo	onents:			
	-	alcohol: radability	:	Result: Readily bi Biodegradation: 9 Exposure time: 14	92 - 96 %
		benzoate: radability	:	Result: Readily bi Biodegradation: 9 Exposure time: 28 Method: Directive	94 %
12.3	Bioaco	cumulative potential			
	<u>Compo</u>	onents:			
	-	alcohol: n coefficient: n- /water	:	log Pow: 1.05	
	-	benzoate: n coefficient: n- /water	:	log Pow: 4 Method: OECD T	est Guideline 117



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

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 (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

Contaminated packaging :	Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer. 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

:	Not regulated as a dangerous good
:	Not regulated as a dangerous good
:	Not regulated as a dangerous good
:	Not regulated as a dangerous good
:	Not regulated as a dangerous good

14.2 UN proper shipping name



Version 1.19	Revision Date: 06.04.2024		ast issue: 30.09.2023 irst issue: 11.12.2015
ADN		: Not regulated as a dangero	us good
ADR		: Not regulated as a dangero	us good
RID		: Not regulated as a dangero	us good
IMDG		: Not regulated as a dangero	us good
ΙΑΤΑ		: Not regulated as a dangero	us good
14.3 Trans	sport hazard class(es		
ADN		: Not regulated as a dangero	us good
ADR		: Not regulated as a dangero	us good
RID		: Not regulated as a dangero	us good
IMDG		: Not regulated as a dangero	us good
ΙΑΤΑ		: Not regulated as a dangero	us good
14.4 Packi	ing group		
ADN		: Not regulated as a dangero	us good
ADR		: Not regulated as a dangero	us good
RID		: Not regulated as a dangero	us good
IMDG		: Not regulated as a dangero	us good
ΙΑΤΑ	(Cargo)	: Not regulated as a dangero	us good
ΙΑΤΑ	(Passenger)	: Not regulated as a dangero	us good
-	onmental hazards gulated as a dangerou	good	
•	ial precautions for us	r	
14.7 Marit Rema	-	ccording to IMO instruments : Not applicable for product a	s 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)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3

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 condiCommission Regulation (EU) 2020/878

Recombinant Bovine Somatotropin Formulation

Version 1.19	Revision Date: 06.04.2024	SDS Number: 413063-00020		f last issue: 30.09.2023 f first issue: 11.12.2015
				tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
	ACH - Candidate List of cern for Authorisation (Substances of Very Hig	h :	Not applicable
Reg		009 on substances that	de- :	Not applicable
Reg		on persistent organic po	ollu- :	Not applicable
Reg mer	ulation (EU) No 649/20	12 of the European Parli erning the export and im		Not applicable
REA	0	s subject to authorisatior	n :	Not applicable
Sev	eso III: Directive 2012/1	8/EU of the European P olving dangerous substa Not applicable		nt and of the Council on the control of

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 H319 H332 H400 H411	:	Harmful if swallowed. Causes serious eye irritation. Harmful if inhaled. Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.
Full text of other abbreviation	ns	
Acute Tox. Aquatic Acute Aquatic Chronic Eye Irrit.	:	Acute toxicity Short-term (acute) aquatic hazard Long-term (chronic) aquatic hazard Eye irritation



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

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 - Emergency 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 m	Classification procedure:	
Eye Irrit. 2	H319	Calculation method
Aquatic Chronic 3	H412	Calculation method

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.



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.19	06.04.2024	413063-00020	Date of first issue: 11.12.2015

IE / EN