

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 9372474-00006 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

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 substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :



SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version 3.2 Revision Date: 30.09.2023 SDS Number: 9372474-00006 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection/ face protection.

Response:
P337 + P313 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.

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 Somatotropin	Not Assigned		>= 20 - < 30
Benzyl benzoate	120-51-4 204-402-9 607-085-00-9	Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 1	>= 10 - < 20
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 10 - < 20

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-

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

- 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 and effects, both acute and delayed

- Risks : Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

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.

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 products : Carbon oxides

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

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 methods : Use extinguishing measures that are appropriate to local circumstances 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 protective 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. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or 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
-

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 9372474-00006 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
Advice on safe handling : Use only with adequate ventilation.
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 assessment
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 contaminated 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)

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 Bovine Somatotropin	Not Assigned	TWA	OEB 3 ($\geq 10 < 100$ $\mu\text{g}/\text{m}^3$)	Internal

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl benzoate	Workers	Inhalation	Long-term systemic effects	5.1 mg/m^3

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version 3.2 Revision Date: 30.09.2023 SDS Number: 9372474-00006 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

	Workers	Inhalation	Acute systemic ef- fects	102 mg/m ³
	Workers	Skin contact	Long-term systemic effects	2.6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.25 mg/m ³
	Consumers	Inhalation	Acute systemic ef- fects	25 mg/m ³
	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/m ³
	Workers	Inhalation	Acute systemic ef- fects	110 mg/m ³
	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/m ³
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m ³
	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):

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
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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 9372474-00006 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

	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 : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : suspension
Colour : opaque, yellow
Odour : musty
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling : No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

range		
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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 products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Recombinant Bovine Somatotropin:

Acute inhalation toxicity : LC50 (Rat): 30,000 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

Benzyl benzoate:

Acute oral toxicity : LD50 (Rat): 1,700 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

Components:

Recombinant Bovine Somatotropin:

Species : Rabbit
Remarks : slight irritation

Benzyl benzoate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Recombinant Bovine Somatotropin:

Species : Rabbit
Remarks : slight irritation

Benzyl benzoate:

Species : Rabbit
Result : No eye irritation

Benzyl alcohol:

Species : Rabbit

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Benzyl benzoate:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

Benzyl alcohol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzyl benzoate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: positive
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with
mammalian liver cells in vivo
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity

Not classified based on available information.

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.

Components:

Benzyl benzoate:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

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 development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Recombinant Bovine Somatotropin:

Species	:	Rat
Exposure time	:	90 d
Remarks	:	No significant adverse effects were reported

Benzyl benzoate:

Species	:	Rat
NOAEL	:	781 mg/kg
Application Route	:	Skin contact
Exposure time	:	4 Weeks

Benzyl alcohol:

Species	:	Rat
NOAEL	:	1.072 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

Components:

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 Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.475 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.247 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 : > 10,000 mg/l
Exposure time: 3 h
Method: ISO 8192

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.258 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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 (Chronic toxicity) : NOEC: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

Benzyl benzoate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 28 d
Method: Directive 67/548/EEC Annex V, C.4.D.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

Benzyl alcohol:

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

12.3 Bioaccumulative potential

Components:

Benzyl benzoate:

Partition coefficient: n-octanol/water : log Pow: 4
Method: OECD Test Guideline 117

Benzyl alcohol:

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

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 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.

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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

Contaminated packaging : Do not dispose of waste into sewer.
: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN 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
IATA : 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
IATA : 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
IATA : Not regulated as a dangerous good

14.4 Packing group

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
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following 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 conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH) : Not 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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302	:	Harmful if swallowed.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H400	:	Very toxic to aquatic life.
H411	:	Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation

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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.2	30.09.2023	9372474-00006	Date of first issue: 27.08.2021

compile the Safety Data
Sheet

eChem Portal search results and European Chemicals Agen-
cy, <http://echa.europa.eu/>

Classification of the mixture:

Eye Irrit. 2	H319
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
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.

GB / EN