

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version 1.18      Revision Date: 30.09.2023      SDS Number: 413063-00019      Date of last issue: 04.04.2023  
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 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  
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      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)

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

---

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version 1.18      Revision Date: 30.09.2023      SDS Number: 413063-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

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.

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 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 <hr/> M-Factor (Acute aquatic toxicity): 1 <hr/> Acute toxicity estimate <hr/> Acute oral toxicity: 1,700 mg/kg	>= 10 - < 20

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version 1.18      Revision Date: 30.09.2023      SDS Number: 413063-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 <hr/> Acute toxicity esti- mate  Acute oral toxicity: 1,620 mg/kg	>= 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 advice 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.

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	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 (CO<sub>2</sub>)  
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

#### 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.  
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.

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

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 CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | Use only with adequate ventilation.  |
| Advice on safe handling | : | Avoid inhalation of vapour or mist.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>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.<br>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:<br>Strong oxidizing agents<br>Gases                  |

### 7.3 Specific end use(s)

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version 1.18      Revision Date: 30.09.2023      SDS Number: 413063-00019      Date of last issue: 04.04.2023  
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 Bovine Somatotropin	Not Assigned	TWA	OEB 3 ( $\geq 10 < 100$ $\mu\text{g}/\text{m}^3$ )	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl benzoate	Workers	Inhalation	Long-term systemic effects	5.1 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	102 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	2.6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.25 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute systemic effects	25 mg/m <sup>3</sup>
	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 effects	78 mg/kg bw/day
	Benzyl alcohol	Workers	Inhalation	Long-term systemic effects
Workers		Inhalation	Acute systemic effects	110 mg/m <sup>3</sup>
Workers		Skin contact	Long-term systemic effects	8 mg/kg bw/day
Workers		Skin contact	Acute systemic effects	40 mg/kg bw/day
Consumers		Inhalation	Long-term systemic effects	5.4 mg/m <sup>3</sup>
Consumers		Inhalation	Acute systemic effects	27 mg/m <sup>3</sup>
Consumers		Skin contact	Long-term systemic effects	4 mg/kg bw/day
Consumers		Skin contact	Acute systemic effects	20 mg/kg bw/day
Consumers		Ingestion	Long-term systemic	4 mg/kg

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version 1.18      Revision Date: 30.09.2023      SDS Number: 413063-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

			effects	bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

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

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 : 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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

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

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
pH	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available



# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

Partition coefficient: n-  
octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

---

## 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 hazard classes as defined in Regulation (EC) No 1272/2008

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

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

#### 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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

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  
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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

### 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

#### **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.

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version 1.18      Revision Date: 30.09.2023      SDS Number: 413063-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

### 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.

#### **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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	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 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  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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

### **Benzyl alcohol:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 230 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 770  
plants : 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 : NOEC: 51 mg/l  
aquatic invertebrates (Chronic : Exposure time: 21 d  
toxicity) : 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.

#### **Benzyl alcohol:**

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

## 12.3 Bioaccumulative potential

### Components:

#### **Benzyl benzoate:**

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

#### **Benzyl alcohol:**

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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	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 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. Do not dispose of waste into sewer.

Contaminated packaging : 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 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

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name



# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

**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

### 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) : 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 condi-

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

tions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

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

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

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

### 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.

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

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	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; AIIIC - 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 compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <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.

# SAFETY DATA SHEET

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



## Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.18	30.09.2023	413063-00019	Date of first issue: 11.12.2015

---

IE / EN