

Recombinant Bovine Somatotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
3.0	28.09.2024	402450-00018	06.04.2024
			Date of first issue: 11.12.2015

SECTION 1: IDENTIFICATION

Product name : Recombinant Bovine Somatotropin Formulation

Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Serious eye damage/eye irritation : Category 2A

Skin sensitisation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P261 Avoid breathing mist or vapours.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ eye protection/ face protection.

**Recombinant Bovine Somatotropin Formula-
tion**

Version 3.0 Revision Date: 28.09.2024 SDS Number: 402450-00018 Date of last issue: 06.04.2024
Date of first issue: 11.12.2015

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Recombinant Bovine Somatotropin	Not Assigned	>= 10 -< 30
Benzyl alcohol	100-51-6	>= 10 -< 30

SECTION 4. 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.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : 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.

**Recombinant Bovine Somatotropin Formula-
tion**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 402450-00018	Date of last issue: 06.04.2024 Date of first issue: 11.12.2015
----------------	------------------------------	-----------------------------	---

Most important symptoms and effects, both acute and delayed	: May cause an allergic skin reaction. Causes serious eye irritation.
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).
Notes to physician	: Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides
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.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for	: Soak up with inert absorbent material.

**Recombinant Bovine Somatotropin Formula-
tion**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 402450-00018	Date of last issue: 06.04.2024 Date of first issue: 11.12.2015
----------------	------------------------------	-----------------------------	---

containment and cleaning up

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.

SECTION 7. HANDLING AND STORAGE

- | | | |
|-----------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Do not get in eyes.
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.
Contaminated work clothing should not be allowed out of the workplace.
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. |
| Conditions for safe storage | : | Keep in properly labelled containers.
Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:
Strong oxidizing agents |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type	Control parame-	Basis
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**Recombinant Bovine Somatotropin Formula-
tion**

Version 3.0 Revision Date: 28.09.2024 SDS Number: 402450-00018 Date of last issue: 06.04.2024
Date of first issue: 11.12.2015

		(Form of exposure)	ters / Permissible concentration	
Recombinant Bovine Somatotropin	Not Assigned	TWA	OEB 3 ($\geq 10 < 100 \mu\text{g}/\text{m}^3$)	Internal

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye 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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : opaque, yellow

Odour : musty

Odour Threshold : No data available

pH : No data available

**Recombinant Bovine Somatotropin Formula-
tion**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 402450-00018	Date of last issue: 06.04.2024 Date of first issue: 11.12.2015
----------------	------------------------------	-----------------------------	---

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	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
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.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

**Recombinant Bovine Somatotropin Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

|| Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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Components:**Recombinant Bovine Somatotropin:**

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

Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

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Components:**Recombinant Bovine Somatotropin:**

**Recombinant Bovine Somatotropin Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

Species	: Rabbit
Remarks	: slight 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 alcohol:

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

Respiratory or skin sensitisation**Skin sensitisation**

|| May cause an allergic skin reaction.

Respiratory sensitisation

|| Not classified based on available information.

Components:**Benzyl alcohol:**

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
Result	: positive

Assessment	: Probability or evidence of low to moderate skin sensitisation rate in humans
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Chronic toxicity**Germ cell mutagenicity**

|| Not classified based on available information.

Components:**Benzyl alcohol:**

**Recombinant Bovine Somatotropin Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

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 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

**Recombinant Bovine Somatotropin Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

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

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

Persistence and degradability**Components:****Benzyl alcohol:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
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**Recombinant Bovine Somatotropin Formula-
tion**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 402450-00018	Date of last issue: 06.04.2024 Date of first issue: 11.12.2015
----------------	------------------------------	-----------------------------	---

II**Bioaccumulative potential****Components:****Benzyl alcohol:**

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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**International Regulations****UNRTDG**

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

IATA-DGR

UN/ID No.	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger aircraft)	: Not applicable

IMDG-Code

UN number	: Not applicable
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**Recombinant Bovine Somatotropin Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**ADG**

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Therapeutic Goods (Poisons Standard) Instrument	:	No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
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Prohibition/Licensing Requirements	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.
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The components of this product are reported in the following inventories:

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

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Revision Date	:	28.09.2024
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**Recombinant Bovine Somatotropin Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

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/>

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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

Recombinant Bovine Somatotropin Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	28.09.2024	402450-00018	Date of first issue: 11.12.2015

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.

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