SAFETY DATA SHEET

Recombinant Bovine Somatotropin Formulation

Section 1: Identification

Product name: Recombinant Bovine Somatotropin Formulation

Manufacturer or supplier's details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTeward@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification
Serious eye damage/eye irritation: 2A

GHS label elements
Hazard pictograms:
Signal word: Warning
Hazard statements: H319 Causes serious eye irritation.
Precautionary statements: Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 IF eye irritation persists: Get medical advice/ attention.
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Recombinant Bovine Somatotropin Formulation

Version 1.9   Revision Date: 13.09.2019   SDS Number: 402598-00010   Date of last issue: 24.04.2019

Date of first issue: 11.12.2015

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant Bovine Somatotropin</td>
<td>Not Assigned</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Benzyl benzoate</td>
<td>120-51-4</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
</tbody>
</table>

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: 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.

Most important symptoms and effects, both acute and delayed: 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: Fire-fighting measures

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

Specific extinguishing method: Use extinguishing measures that are appropriate to local cir-
Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions

Discharge into the environment must be avoided. 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 containment and 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.

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

Avoid inhalation of vapour or mist. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. 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.

**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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant Bovine Somatotropin</td>
<td>Not Assigned</td>
<td>TWA</td>
<td>OEB 3 (&gt;= 10 &lt; 100 µg/m3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

#### 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

**Eye protection**
- **Remarks**
  - Consider double gloving.
  - 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**
- **Remarks**
  - Work uniform or laboratory coat.
  - Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-
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
- **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
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

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

Chronic toxicity

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

**Benzyl alcohol:**
- **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
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.

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

**Ecotoxicity**

**Components:**

**Benzyl benzoate:**

- **Toxicity to fish**
  - LC50 (Danio rerio (zebra fish)): 2.32 mg/l
  - Exposure time: 96 h

- **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

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

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

**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 benzoate**:
- **Biodegradability**: Result: Readily biodegradable.  
  Biodegradation: 94 %  
  Exposure time: 28 d  

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

**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
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Section 13: Disposal considerations

Disposal methods
Waste from residues: 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  Not regulated as a dangerous good
IATA-DGR  Not regulated as a dangerous good
IMDG-Code  Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433  Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS  :  not determined
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Recombinant Bovine Somatotropin Formula-
tion

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<table>
<thead>
<tr>
<th>DSL</th>
<th>not determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

Section 16: Other information

Further information

Sources of key data used to compile the Safety Data Sheet:


Date format: dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 Chemicals 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 - Philips 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; 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 mate-
<table>
<thead>
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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.

NZ / EN