Recombinant Bovine Somatotropin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Recombinant Bovine Somatotropin Formulation

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: suspension
Colour: opaque, yellow
Odour: musty
Causes serious eye irritation. Toxic to aquatic life. Harmful to aquatic life with long lasting effects.

GHS Classification

Serious eye damage/eye irritation: Category 2A
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 3

GHS label elements

Hazard pictograms:

Signal word: Warning

Hazard statements: H319 Causes serious eye irritation.
H401 Toxic to aquatic life.
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:**
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.

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

### Physical and chemical hazards
Not classified based on available information.

### Health hazards
Causes serious eye irritation.

### Environmental hazards
Toxic to aquatic life. Harmful to aquatic life with long lasting effects.

### Other hazards which do not result in classification
None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

### 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;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Benzyl benzoate</td>
<td>120-51-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

## 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...
## 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters</td>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
</tbody>
</table>

## 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
<td></td>
</tr>
<tr>
<td>Environmental precautions</td>
<td>Avoid release to the environment.</td>
</tr>
<tr>
<td>Prevent further leakage or spillage if safe to do so.</td>
<td></td>
</tr>
<tr>
<td>Prevent spreading over a wide area (e.g. by containment or oil barriers).</td>
<td></td>
</tr>
<tr>
<td>Retain and dispose of contaminated wash water.</td>
<td></td>
</tr>
<tr>
<td>Local authorities should be advised if significant spillages cannot be contained.</td>
<td></td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
<td>Soak up with inert absorbent material.</td>
</tr>
<tr>
<td>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can</td>
<td></td>
</tr>
</tbody>
</table>
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.

7. HANDLING AND STORAGE

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.
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.
Avoidance of contact: Oxidizing agents

Storage
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

Packaging material: Unsuitable material: None known.

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., dripless 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
- **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.

**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.

**Hand protection**

- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>opaque, yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>musty</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Recombinant Bovine Somatotropin Formula-
tion

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.

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: > 5,000 mg/kg
  Method: Calculation method
- Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
- Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

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

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

Benzy! 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
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<td>402503-00011</td>
<td>2019/09/13</td>
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</table>

## 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
- **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
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</table>

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

**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

**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
Recombinant Bovine Somatotropin Formulation

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.

**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

M-Factor (Acute aquatic toxicity): 1

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  
Exposure time: 3 h  
Method: ISO 8192

**Benzyl alcohol:**
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
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</tbody>
</table>

- **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

**Mobility in soil**

No data available
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Other adverse effects
No data available

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.

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

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Recombinant Bovine Somatotropin Formula-

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

Date format: yyyy/mm/dd

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; 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

Disclaimer
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.

CN / EN