



# SAFETY DATA SHEET

## 1. Identification

|                                      |  |
|--------------------------------------|--|
| <b>Product identifier</b>            | <b>Humatrope®</b>  |
| <b>Other means of identification</b> |  |
| <b>Item Code</b>                     | MS5107, MS8970, MS8093, MS8097, VL7335, MS8099, MS8086, MS9551, MS8052, MS8053, MS9550, MS9549, MS8091, MS9548, MS8096, MS8147, MS8092, MS8090, VL7365, VL7384, VL7554, VL7555, VL7556, MS8051, MS8087, MS8088, MS8089, MS9562, MS9561, MS9560 |
| <b>LY Number</b>                     | LY137998   |
| <b>Recommended use</b>               | Pharmaceutical   |
| <b>Recommended restrictions</b>      | None known.  |

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

|                               |   |                 |  |
|-------------------------------|---|-----------------|--|
| <b>Company name</b>           | Eli Lilly and Company   |                 |  |
| <b>Address</b>                | Lilly Corporate Center<br>Indianapolis, IN 46285<br>United States |                 |  |
| <b>Telephone</b>              | Phone:  | +1-317-276-2000 |  |
| <b>E-mail</b>                 | lilly_msds@lilly.com  |                 |  |
| <b>Emergency phone number</b> | CHEMTREC:   | +1-800-424-9300 |  |

## 2. Hazard(s) identification

|                             |                 |
|-----------------------------|-----------------|
| <b>Physical hazards</b>     | Not classified. |
| <b>Health hazards</b>       | Not classified. |
| <b>OSHA defined hazards</b> | Not classified. |

#### Label elements

|  |  |
|--|--|
| <b>Hazard symbol</b>                             | None.  |
| <b>Signal word</b>                               | None.  |
| <b>Hazard statement</b>                          | The mixture does not meet the criteria for classification. |
| <b>Precautionary statement</b>                   |  |
| <b>Prevention</b>                                | Not available.   |
| <b>Response</b>                                  | Not available.   |
| <b>Storage</b>                                   | Not available.   |
| <b>Disposal</b>                                  | Not available.   |
| <b>Hazard(s) not otherwise classified (HNOC)</b> | None known.  |
| <b>Supplemental information</b>                  | Not applicable.  |

## 3. Composition/information on ingredients

#### Mixtures

| <b>Chemical name</b> | <b>Common name and synonyms</b> | <b>CAS number</b> | <b>%</b> |
|----------------------|---------------------------------|-------------------|----------|
| Somatropin           |                                 | 12629-01-5        | 13.8     |

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## 4. First-aid measures

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.  |
| <b>Skin contact</b> | Wash off with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists. |
| <b>Eye contact</b>  | In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.                      |

**Ingestion** Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

**Most important symptoms/effects, acute and delayed** Somatotropin is identical to the naturally occurring hormone which stimulates growth and muscle development.

## 5. Fire-fighting measures

**Suitable extinguishing media** Carbon dioxide, dry chemical or water.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical** Hazardous decomposition products formed under fire conditions.

**Special protective equipment and precautions for firefighters** Wear self-contained breathing apparatus and protective clothing.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Wear suitable protective clothing, gloves and eye/face protection.

**Methods and materials for containment and cleaning up** Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** Avoid contact with eyes, skin, and clothing. See Section 8 of the SDS for Personal Protective Equipment.

**Conditions for safe storage, including any incompatibilities** Keep refrigerated

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Lilly (LEG)

#### Components

Somatropin (CAS 12629-01-5)

#### Type

TWA (12hrs)

#### Value

86 ug/m3

#### Form

Respirable dust

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Exposure guidelines** Excursion Limit is 12 times full shift TWA for no more than 30 minutes not to exceed full shift guideline.

**Appropriate engineering controls** Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear goggles/face shield.

#### Skin protection

##### Hand protection

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

##### Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

#### Respiratory protection

Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator.

**Thermal hazards** Not available.

## 9. Physical and chemical properties

### Appearance

**Physical state** Solid.

**Form** Solid. (Lyophilized).

**Color** White

|   |  |
|---|--|
| <b>Odor</b>   | Odorless   |
| <b>Odor threshold</b>                               | No data available.                                       |
| <b>pH</b>   | 6.5 - 8.5  |
| <b>Melting point/freezing point</b>                 | No data available.                                       |
| <b>Initial boiling point and boiling range</b>      | No data available.                                       |
| <b>Flash point</b>                                  | No data available.                                       |
| <b>Evaporation rate</b>                             | No data available.                                       |
| <b>Flammability (solid, gas)</b>                    | No test data available.                                  |
| <b>Upper/lower flammability or explosive limits</b> |  |
| <b>Flammability limit - lower (%)</b>               | No data available.                                       |
| <b>Flammability limit - upper (%)</b>               | No data available.                                       |
| <b>Explosive limit - lower (%)</b>                  | No data available.                                       |
| <b>Explosive limit - upper (%)</b>                  | No data available.                                       |
| <b>Vapor pressure</b>                               | No data available.                                       |
| <b>Vapor density</b>                                | No data available.                                       |
| <b>Relative density</b>                             | No data available.                                       |
| <b>Solubility(ies)</b>                              |  |
| <b>Solubility (water)</b>                           | Soluble  |
| <b>Partition coefficient (n-octanol/water)</b>      | No data available.                                       |
| <b>Auto-ignition temperature</b>                    | No data available.                                       |
| <b>Decomposition temperature</b>                    | No data available.                                       |
| <b>Viscosity</b>                                    | Not applicable.  |
| <b>Other information</b>                            |  |
| <b>Density</b>                                      | No data available.                                       |
| <b>Explosive properties</b>                         | Not explosive.   |
| <b>Oxidizing properties</b>                         | The substance or mixture is not classified as oxidizing. |
| <b>Percent volatile</b>                             | No data available.                                       |
| <b>VOC</b>  | No data available.                                       |

## 10. Stability and reactivity

|   |  |
|---|--|
| <b>Reactivity</b>                         | Not water reactive.  |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.                    |
| <b>Possibility of hazardous reactions</b> | Hazardous polymerization does not occur.                       |
| <b>Conditions to avoid</b>                | None known.  |
| <b>Incompatible materials</b>             | Strong oxidizing substances.                                   |
| <b>Hazardous decomposition products</b>   | Hazardous decomposition products formed under fire conditions. |

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

| Components                  | Species | Test Results   |
|-----------------------------|---------|--|
| Somatropin (CAS 12629-01-5) |         |  |
| <b>Acute</b>                |         |  |
| <b>Inhalation</b>           |         |  |
| LC50                        | Rat     | > 0.27 mg/m <sup>3</sup> , 18 min , No toxicity. No mortality. |

| Components  | Species  | Test Results                             |
|---|--|--|
| <b>Oral</b>   |  |  |
| LD  | Rat  | > 150 mg/kg , No toxicity. No mortality. |
| <b>Other</b>  |  |  |
| LD  | Monkey   | > 6.25 mg/kg , Subcutaneous              |
|   | Rat  | > 12.5 mg/kg , Intravenous               |
| <b>Skin corrosion/irritation</b>  | Due to lack of data the classification is not possible.  |  |
| <b>Serious eye damage/eye irritation</b>  | Rabbit: Slight irritation. (cleared within 7 days) (Somatropin)<br>Based on available data, the classification criteria are not met.   |  |
| <b>Respiratory or skin sensitization</b>  |  |  |
| <b>Respiratory sensitization</b>  | Due to lack of data the classification is not possible.  |  |
| <b>Skin sensitization</b>   | Due to lack of data the classification is not possible.  |  |
| <b>Germ cell mutagenicity</b>   | Result in genetic toxicity assays (in vitro and in vivo): Negative (Somatropin)<br>Based on available data, the classification criteria are not met.   |  |
| <b>Carcinogenicity</b>  | Due to lack of data the classification is not possible.  |  |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>                   | Not listed.  |  |
| <b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)</b>           | Not regulated.   |  |
| <b>US. National Toxicology Program (NTP) Report on Carcinogens</b>              | Not listed.  |  |
| <b>Reproductive toxicity</b>  | Prolonged estrous cycle, increased litter size and fetal weight at doses toxic to the mother. (growth hormone)<br>Based on available data, the classification criteria are not met.  |  |
| <b>Specific target organ toxicity - single exposure</b>                         | Due to lack of data the classification is not possible.  |  |
| <b>Specific target organ toxicity - repeated exposure</b>                       | Metabolic effects (increased body weight, increased food consumption, increased number of bone marrow osteoblasts, increased serum alkaline phosphatase, change in protein, carbohydrate, and fat metabolism, increased number and size of muscle cell). Increased heart weights were reported in male Rhesus monkeys administered inhalation doses of 12.3 mg/kg/day for 6 months. (Somatropin) Based on available data, the classification criteria are not met. |  |
| <b>Aspiration hazard</b>  | No aspiration toxicity classification  |  |
| <b>Further information</b>  | Somatropin is identical to the naturally occurring hormone which stimulates growth and muscle development.   |  |
| <b>12. Ecological information</b>   |  |  |
| <b>Ecotoxicity</b>  | Due to lack of data the classification is not possible.  |  |
| <b>Persistence and degradability</b>  | No data is available on the degradability of this product.   |  |
| <b>Bioaccumulative potential</b>  | No data available on bioaccumulation.  |  |
| <b>Mobility in soil</b>   | No data available for this product.  |  |
| <b>Other adverse effects</b>  | Not available.   |  |
| <b>13. Disposal considerations</b>  |  |  |
| <b>Disposal instructions</b>  | Dispose of contents/container in accordance with local/regional/national/international regulations.  |  |
| <b>14. Transport information</b>  |  |  |
| <b>DOT</b>  | Not regulated as dangerous goods.  |  |
| <b>IATA</b>   | Not regulated as dangerous goods.  |  |
| <b>IMDG</b>   | Not regulated as dangerous goods.  |  |
| <b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b> | Not applicable.  |  |

## 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
One or more components are not listed on TSCA.  
CERCLA/SARA Hazardous Substances - Not applicable.

### Toxic Substances Control Act (TSCA)

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

### US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

| Country(s) or region        | Inventory name                                | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Canada                      | Domestic Substances List (DSL)                | No                     |
| Canada                      | Non-Domestic Substances List (NDSL)           | No                     |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No                     |

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 11-20-2014  
**Revision date** 01-17-2019  
**Version #** 03

**List of abbreviations** LEG: Lilly Exposure Guideline.  
TWA: Time Weighted Average

**Disclaimer** As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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