



SAFETY DATA SHEET

1. Identification

Product identifier	Humatrope®		
Other means of identification			
Item Code	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		
Recommended use	Pharmaceutical		
Recommended restrictions	None known.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	Eli Lilly and Company		
Address	Lilly Corporate Center Indianapolis, IN 46285 United States		
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E-mail	lilly_msds@lilly.com		
Emergency phone number	CHEMTREC:	+1-800-424-9300	

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Not applicable.

3. Composition/information on ingredients

Mixtures			
Chemical name	Common name and synonyms	CAS number	%
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

Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
Skin contact	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.

Eye contact	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	Somatropin 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

	Type	Value	Form
Somatropin (CAS 12629-01-5)	TWA (12hrs)	86 ug/m3	Respirable dust

Occupational exposure limits	No exposure limits noted for ingredient(s).
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.
Thermal hazards	Not available.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Solid. (Lyophilized).
Color	White
Odor	Odorless
Odor threshold	No data available.
pH	6.5 - 8.5
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)	No test data available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit - upper (%)	No data available.

Vapor pressure No data available.

Vapor density No data available.

Relative density No data available.

Solubility(ies)

Solubility (water) Soluble

Partition coefficient (n-octanol/water) No data available.

Auto-ignition temperature No data available.

Decomposition temperature No data available.

Viscosity Not applicable.

Other information

Density No data available.

Explosive properties Not explosive

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

Percent volatile No data available.

VOC (Weight %) No data available.

10. Stability and reactivity

Reactivity Not water reactive.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions Hazardous polymerization does not occur.

Conditions to avoid None known.

Incompatible materials Strong oxidizing substances.

Hazardous decomposition products 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)		
<u>Acute</u>		
Inhalation		
LC50	Rat	> 0.27 mg/m3, 18 min , No toxicity. No mortality.
Oral		
LD	Rat	> 150 mg/kg , No toxicity. No mortality.
Other		
LD	Monkey	> 6.25 mg/kg , Subcutaneous
	Rat	> 12.5 mg/kg , Intravenous
Skin corrosion/irritation	Due to lack of data the classification is not possible.	
Serious eye damage/eye irritation	Rabbit: Slight irritation. (cleared within 7 days) (Somatropin) Based on available data, the classification criteria are not met.	
Respiratory or skin sensitization		
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	Result in genetic toxicity assays (in vitro and in vivo): Negative (Somatropin) Based on available data, the classification criteria are not met.	
Carcinogenicity	Not listed by IARC, NTP, ACGIH or OSHA. Due to lack of data the classification is not possible.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	Prolonged estrous cycle, increased litter size and fetal weight at doses toxic to the mother. (growth hormone) Based on available data, the classification criteria are not met.	
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	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.	
Aspiration hazard	No aspiration toxicity classification	
Further information	Somatropin is identical to the naturally occurring hormone which stimulates growth and muscle development.	

12. Ecological information

Ecotoxicity	Due to lack of data the classification is not possible.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available on bioaccumulation.
Mobility in soil	No data available for this product.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
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14. Transport information**DOT**

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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.

Safe Drinking Water Act (SDWA) 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.

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

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

Country(s) or region	Inventory name	On inventory (yes/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	03-12-2015
Version #	02
Lilly Lab Code	Health: 0 Fire: 1 Reactivity: 0

List of abbreviations	LEG: Lilly Exposure Guideline TWA: Time Weighted Average
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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 MATERIAL 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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For additional information contact:
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Revision Information	Product and Company Identification: Alternate Trade Names Exposure controls/personal protection: Appropriate engineering controls Other information, including date of preparation or last revision: List of abbreviations
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