



Somatropin for Injection

Effective Date: 30-Sep-2007

Eli Lilly and Company
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:

Eli Lilly and Company
 Lilly Corporate Center
 Indianapolis, IN 46285

Manufacturer's Emergency Phone:

1-317-276-2000

CHEMTREC:

1-800-424-9300 (North America)

1-703-527-3887 (International)

Common Name: Somatropin for Injection

Chemical Name: Somatotropin (human)

Synonym(s): 137998 Formulation; Biosynthetic Human Growth Hormone for Injection; Somatropin (rDNA Origin) for Injection; Biosynthetic 2 Cistron Human Growth Hormone Cystine; hGH; Somatropin; Somatotropin; Human Growth Hormone, Biosynthetic; Growth Hormone, Human

Trademarks(s): Hutrope; Umatrope; Lilly Humatrope; Humax; Humatrope

Lilly Item Code(s): MS5107; MS8051; MS8052; MS8053; MS8086; MS8087; MS8088; MS8089; MS8090; MS8091; MS8092; MS8093; MS8096; MS8097; MS8098; MS8099; MS8145; MS8146; MS8147; MS8970; MS8973; MS9546; MS9547; MS9548; MS9549; MS9550; MS9551; RV7338; RV7339; VL7330; VL7332; VL7335; VL7346; VL7348; VL7351; VL7353; VL7354; VL7360; VL7362; VL7365; VL7372; VL7384; VL7386; VL7418; VL7518; VL7520; VL7522; VL7524; VL7525; VL7554; VL7555; VL7556; VL7605

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Somatropin	12629-01-5	13.8
Mannitol	69-65-8	69.2
Glycine	56-40-6	13.2
Sodium Phosphate Dibasic Heptahydrate	7782-85-6	3

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines:

Somatropin - LEG 86 micrograms/m³ TWA (respirable) for 12 hours. If respirable sampling is not possible, assume total particulate methods.

Mannitol - Exposure Guideline 10 mg/m³ TWA for 8 or 12 hours.

Sodium phosphate dibasic anhydrous - Exposure Guideline 1 mg/m³ TWA for 8 hours, 3 mg/m³ TWA

for 15 minutes STEG (Lilly-established guideline).

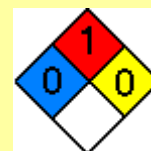
Section 3 - Hazards Identification

Appearance: White lyophilized plug or powder

Physical State: Solid

Odor: Odorless

Emergency Overview



Emergency Overview Effective Date: 01-Sep-2000

Lilly Laboratory Labeling Codes:

Health 0

Fire 1

Reactivity 0

Primary Physical and Health Hazards: Hormonal Effects.

Caution Statement: Effects of exposure to Somatropin for Injection may include changes in hormone levels.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: None reported; however, somatropin is identical to the naturally occurring hormone which stimulates growth and muscle development. Dilute formulations of somatropin and glycine are not expected to be irritating to the eyes.

Medical Conditions Aggravated by Exposure: None known.

Carcinogenicity:

Mannitol - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year dietary studies demonstrated no evidence of carcinogenicity in mice and rats.

Glycine - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year oral studies demonstrated no evidence of carcinogenicity in rats.

Remaining ingredients - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Sodium phosphate dibasic anhydrous is a CERCLA Hazardous Substance.

Section 7 - Handling and Storage

Storage Conditions: Keep refrigerated.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved respirator.

Eye Protection: Safety glasses.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Section 9 - Physical and Chemical Properties

Appearance: White lyophilized plug or powder

Odor: Odorless

Boiling Point: Not applicable

Melting Point: No applicable information found

Density: No applicable information found

pH: 6.5-8.5 (reconstituted)

Evaporation Rate: No applicable information found

Water Solubility: Soluble

Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Oral:

Somatropin - Rat, 150 mg/kg, no deaths or toxicity.

Skin: No applicable information found.

Inhalation:

Somatropin - Rat, 0.27 mg/m³ for 18 minutes, no deaths or toxicity.

Intravenous:

Somatropin - Rat, 12.5 mg/kg, no deaths or toxicity.

Subcutaneous:

Somatropin - Monkey, 6.25 mg/kg, no deaths or toxicity.

Skin Contact: No applicable information found.

Eye Contact:

Somatropin - Rabbit, slight irritant

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Target Organ Effects:

Somatropin - 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.

Reproduction:

Growth hormone - Prolonged estrous cycle, increased litter size and fetal weight at doses toxic to the mother.

Sensitization: No applicable information found.

Mutagenicity:

Somatropin - Negative in bacterial and mammalian cells.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

Environmental Summary:

Mannitol - Material is not expected to be toxic to aquatic organisms. Material is expected to exist in the particulate phase if released into the air. Material is expected to have very high mobility in soil and is not expected to volatilize from aquatic environments. Material is not expected to bioconcentrate in aquatic organisms. Material is a simple sugar alcohol and should be readily biodegraded.

Glycine - Material is not considered to be bioaccumulative. Material is soluble in water and is expected to leach from soil into groundwater.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

Somatropin and glycine

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Mannitol

TSCA - Yes

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Sodium phosphate dibasic anhydrous

TSCA - Yes

CERCLA - Name on list is sodium phosphate dibasic. RQ=5000 pounds (2270 kg)

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

EU Regulations

EC Classification

Not assigned an overall EC classification.

Section 16 - Other Information

MSDS Sections Revised: Section 7.

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 MERCHANTABILITY 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.

For additional information contact:

Eli Lilly and Company
Hazard Communication
317-277-6029

For additional copies contact:

Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act

STEG = Lilly Short Term Exposure Guideline

STEL = Short Term Exposure Limit

TLV = Threshold Limit Value (ACGIH)

TPQ = Threshold Planning Quantity

TSCA = Toxic Substances Control Act

TWA = Time Weighted Average/8 Hours Unless Otherwise Noted

UEL = Upper Explosive Limit

UN = United Nations

WEEL = Workplace Environmental Exposure Level (AIHA)