



# SAFETY DATA SHEET

Revision date: 15-Mar-2018

Version: 4.0

Page 1 of 9

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)**

**Trade Name:** Genotropin Miniquick; Genotropin MQ  
**Synonyms:** Human Growth Hormone; HGH; Somatotropin  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product for the treatment of human growth hormone deficiency.

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4  
Skin Sensitization: Category 1  
Reproductive Toxicity: Category 2

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H302 - Harmful if swallowed  
H317 - May cause an allergic skin reaction  
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.  
May form combustible dust concentrations in air

## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 2 of 9

Version: 4.0

**Precautionary Statements:**

- P202 - Do not handle until all safety precautions have been read and understood
- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P272 - Contaminated work clothing must not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P330 - Rinse mouth
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P363 - Wash contaminated clothing before reuse
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Somatropin	12629-01-5	235-735-8	Acute Tox. 3 (H301) Acute Tox. 4 (H312, H332) Skin Sens. 1 (H317) Repr. 2 (H361fd)	12 - 22

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Glycine	56-40-6	200-272-2	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 3 of 9

Version: 4.0

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 4 of 9

Version: 4.0

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Somatropin

**Pfizer OEL TWA-8 Hr:** 10µg/m<sup>3</sup>, Sensitizer

#### Glycine

**Latvia OEL - TWA** 5 mg/m<sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Sodium phosphate, dibasic

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Sodium phosphate, monobasic

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 5 of 9

Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
<b>Respiratory protection:</b>	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Lyophilized powder plus sterile diluent	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### Water

No data available

#### Mannitol

No data available

#### Glycine

No data available

#### Sodium phosphate, dibasic

No data available

#### Sodium phosphate, monobasic

No data available

#### Somatropin

No data available

**Decomposition Temperature (°C):** No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 6 of 9

Version: 4.0

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.  
**Long Term:** Animal studies indicate that this material may cause adverse effects on the blood, kidneys, liver, mammary gland.  
**Known Clinical Effects:** Adverse effects associated with therapeutic use include glucose intolerance, fluid retention, headache and effects on the thyroid. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Drugs of this class may cause formation of antibodies.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Mannitol**

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

##### **Glycine**

Rat Oral LD 50 7930 mg/kg  
Mouse Oral LD 50 4920mg/kg

##### **Somatropin**

Rat Oral LD50 242 mg/kg  
Rat Dermal LD50 1100mg/kg  
Rat Inhalation LC50 1h 710mg/m<sup>3</sup>  
Mouse Oral LD50 828mg/kg  
Mouse Intraperitoneal LD50 828mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Somatropin**

Skin Irritation Rabbit Negative  
Not specified Guinea Pig Positive  
Antigenicity- Active anaphylaxis Guinea Pig Positive  
Antigenicity- Passive cutaneous anaphylaxis Guinea Pig Positive

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **Somatropin**

1 Month(s) Rat Intramuscular 0.63 mg/kg/day NOAEL Mammary gland

## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 7 of 9

Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

3 Month(s)	Rat	Subcutaneous	0.37 mg/kg/day	LOEL	Liver, Adrenal gland, Kidney
3 Month(s)	Monkey	Subcutaneous	0.125 mg/kg/day	LOEL	Mammary gland, Blood
52 Week(s)	Monkey	Subcutaneous	0.63 mg/kg/day	NOEL	Adipose tissue, Mammary gland, Reproductive system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Somatropin

Embryo / Fetal Development	Rat	Subcutaneous	3.3 mg/kg/day	NOEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.3 mg/kg/day	NOEL	Not Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	3.3 mg/kg/day	LOEL	Fetotoxicity
Reproductive & Fertility	Rat	Subcutaneous	0.3 mg/kg/day	NOEL	Fertility
Peri-/Postnatal Development	Rat	Subcutaneous	3.3 mg/kg/day	NOEL	No effects at maximum dose

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Somatropin

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vivo</i> Chromosome Aberration	Rat Bone Marrow	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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## SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)  
Revision date: 15-Mar-2018

Page 8 of 9

Version: 4.0

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Somatropin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	235-735-8

#### Glycine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-272-2

#### Mannitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

#### Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

#### Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
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## SAFETY DATA SHEET

**Material Name: Somatropin For Injection (Single Dose Syringe: 0.2mg - 0.4mg)**  
**Revision date: 15-Mar-2018**

**Page 9 of 9**

**Version: 4.0**

### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-449-2

#### Water

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Acute toxicity, dermal-Cat.4; H312 - Harmful in contact with skin  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 15-Mar-2018  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**