



# SAFETY DATA SHEET

Revision date: 29-May-2015

Version: 3.0

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

### Product Identifier

**Material Name: Somatropin For Injection (Single Dose Syringe: 0.6mg - 2.0mg)**

**Trade Name:** Genotropin Miniquick®; Genotonorm 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  
Acute Dermal Toxicity: Category 4  
Acute Toxicity - Dusts and Mists: Category 4  
Skin Sensitization: Category 1  
Reproductive Toxicity: Category 2

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

#### EU Classification:

EU Indication of danger: Harmful  
Toxic to Reproduction: Category 3

#### EU Risk Phrases:

R43 - May cause sensitization by skin contact.  
R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.  
R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.

### Label Elements

**Signal Word:** Warning

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### 2. HAZARDS IDENTIFICATION

**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  
 H312 - Harmful in contact with skin  
 H332 - Harmful if inhaled

**Precautionary Statements:**  
 P201 - Obtain special instructions before use  
 P202 - Do not handle until all safety precautions have been read and understood  
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
 P264 - Wash hands thoroughly after handling  
 P270 - Do not eat, drink or smoke when using this product  
 P271 - Use only outdoors or in a well-ventilated area  
 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  
 P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
 P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
 P308 + P313 - IF exposed or concerned: Get medical attention/advice  
 P312 - Call a POISON CENTRE/doctor/physician if you feel unwell  
 P363 - Wash contaminated clothing before reuse  
 P405 - Store locked up  
 P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
 Hazardous Substance. Non-Dangerous Goods.

**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	EU Classification	GHS Classification	%

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Somatropin	12629-01-5	235-735-8	Xn;R20/21/22 Repr.Cat.3;R62-63 Xi;R43	Acute Tox. 3 (H301) Acute Tox. 4 (H312, H332) Skin Sens. 1 (H317) Repr. 2 (H361fd)	30 - 59
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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	Not Listed	*
Glycine	56-40-6	200-272-2	Not Listed	Not Listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	Not Listed	*

**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 R phrases and 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:** No data available

**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**

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**Hazardous Combustion Products:** No data available

**Fire / Explosion Hazards:** Not available

### Advice for Fire-Fighters

During all fire fighting 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

**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. Clean up 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.

**Incompatible Materials:** None identified

**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 exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

### 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).

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** 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.

### 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

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

#### 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.

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

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.

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### 10. STABILITY AND REACTIVITY

#### 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:** None identified  
**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 NOEL Mammary gland  
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

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### 11. TOXICOLOGICAL INFORMATION

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

##### **Somatropin**

Embryo / Fetal Development	Rat	Subcutaneous	3.3 mg/kg/day	NOAEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.3 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	3.3 mg/kg/day	LOAEL	Fetotoxicity
Reproductive & Fertility	Rat	Subcutaneous	0.3 mg/kg/day	NOAEL	Fertility
Peri-/Postnatal Development	Rat	Subcutaneous	3.3 mg/kg/day	NOAEL	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

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** 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.

### 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.

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### 15. REGULATORY INFORMATION

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

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

D1b toxic materials  
D2a very toxic materials  
D2b toxic materials



#### 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

#### 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

#### Sodium phosphate, monobasic

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present



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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-449-2

#### Sodium phosphate, dibasic

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

#### 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 R phrases and 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.

Toxic to Reproduction: Category 3

Xi - Irritant

Xn - Harmful

R22 - Harmful if swallowed.

R43 - May cause sensitization by skin contact.

R62 - Possible risk of impaired fertility.

R63 - Possible risk of harm to the unborn child.

R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information. Updated Section 7 - Handling and Storage.

**Revision date:** 29-May-2015

Product Stewardship Hazard Communication

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

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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**