



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: 0.6mg - 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

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

SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.6mg - 2.0mg)
Revision date: 15-Mar-2018

Page 2 of 9

Version: 4.0

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 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

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)	30 - 59

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: 0.6mg - 2.0mg)
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: 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

Hazardous Combustion Products: No data available

Fire / Explosion Hazards: Not available

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: 0.6mg - 2.0mg)
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.

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/m³, Sensitizer

Glycine

Latvia OEL - TWA 5 mg/m³

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/m³ to 3000ug/m³)

Sodium phosphate, monobasic

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

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: 0.6mg - 2.0mg)
Revision date: 15-Mar-2018

Page 5 of 9

Version: 4.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands:	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.)
Eyes:	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.)
Skin:	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.)
Respiratory protection:	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

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

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

SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.6mg - 2.0mg)
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: 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/m³
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

SAFETY DATA SHEET

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

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.
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SAFETY DATA SHEET

Material Name: Somatropin For Injection (Single Dose Syringe: 0.6mg - 2.0mg)
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: 0.6mg - 2.0mg)
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. Publicly available toxicity information.

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