MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

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

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CT13 9NJ
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ChemSafe (24 hours): +44 (0)208 762 8322

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

Trade Name:	Genotropin Miniquick®
Synonyms:	Human Growth Hormone; HGH; Somatotropin
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product for the treatment of human growth hormone deficiency

2. HAZARDS IDENTIFICATION

Appearance: White sterile lyophilized powder plus sterile diluent
Signal Word: DANGER

Statement of Hazard:
Toxic if swallowed.
May cause allergic skin reaction.
Suspected of damaging fertility or the unborn child.

Additional Hazard Information:
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

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

EU Hazard Symbols:

EU Risk Phrases:
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.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	%
Somatropin	12629-01-5	235-735-8	Xn;R22 Repr.Cat.3;R62-63 Xi;R43	30 - 59

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

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: No data available

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not available

6. ACCIDENTAL RELEASE MEASURES

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

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.

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

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

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Somatropin

Pfizer OEL TWA-8 Hr: 10µg/m^3, Sensitizer

Glycine

Latvia OEL - TWA Listed

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

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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

Physical State:	Lyophilized powder plus sterile diluent	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: No data available
Incompatible Materials: None identified

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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 4920 mg/kg

Sodium phosphate, dibasic
Rat Oral LD 50 17 g/kg

Sodium phosphate, monobasic
Rat Oral LD 50 8290 mg/kg

Somatropin
Rat Oral LD50 242 mg/kg
Rat Dermal LD50 1100 mg/kg
Rat Inhalation LC50 1h 710 mg/m^3
Mouse Oral LD50 828 mg/kg
Mouse Intraperitoneal LD50 828 mg/kg

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

Sodium phosphate, dibasic
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Somatropin
Skin Irritation Rabbit Negative
Not specified Guinea Pig Positive

11. TOXICOLOGICAL INFORMATION

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
3 Month(s)	Rat	Subcutaneous	0.37 mg/kg/day	LOAEL	Liver, Adrenal gland, Kidney
3 Month(s)	Monkey	Subcutaneous	0.125 mg/kg/day	LOAEL	Mammary gland, Blood
52 Week(s)	Monkey	Subcutaneous	0.63 mg/kg/day	NOAEL	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	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)	*Salmonella* , *E. coli*	Negative
In Vitro Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
In Vivo Chromosome Aberration	Rat Bone Marrow	Negative
In Vitro 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.

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

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

15. REGULATORY INFORMATION

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

EU Risk Phrases:

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.

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Toxic if swallowed.
May cause allergic skin reaction.
Suspected of damaging fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
D1b toxic materials
D2a very toxic materials
D2b toxic materials

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Somatropin

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	235-735-8

Glycine

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	200-272-2

Sodium phosphate, monobasic

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-449-2

Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-448-7

Water

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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.

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.

Prepared by: Toxicology and Hazard Communication
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