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

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Somatropin Solution For Injection

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Somatropin	12629-01-5	235-735-8	5mg;12mg####
m-Cresol	108-39-4	203-577-9	*

Ingredient	CAS Number	EU EINECS List	%
Glycine	56-40-6	200-272-2	*
Mannitol	69-65-8	200-711-8	*
Sodium Phosphate	7632-05-5	231-558-5	*
Water	7732-18-5	231-791-2	*

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

3. 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:
Short Term: May cause eye irritation (based on components)
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 the 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 Indication of danger:
Harmful
Irritant
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.

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.

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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Somatropin

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

m-Cresol

OSHA - Final PELS - TWAs:	= 22 mg/m^3 TWA = 5 ppm TWA
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
ACGIH Threshold Limit Value (TWA)	= 5 ppm TWA
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	= 22 mg/m^3 TWA = 5 ppm TWA

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.

Personal Protective Equipment:

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

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)

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

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

m-Cresol
Rat Oral LD50 242 mg/kg
Rabbit Dermal LD50 2050 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)

m-Cresol
Skin Irritation Rabbit Severe
Eye Irritation Rabbit Severe

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
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

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

m-Cresol

RCRA - U Series Wastes waste number U052

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
Irritant
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:

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

Somatropin

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

Glycine

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-272-2

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

m-Cresol

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 100 lb final RQ = 45.4 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS List	203-577-9

Sodium Phosphate

Inventory - United States TSCA - Sect. 8(b)	Present

Australia (AICS):	Present
EU EINECS List	231-558-5

Water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Added Pfizer OEL (Section 8). Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet