# MATERIAL SAFETY DATA SHEET



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

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## Material Name: Somatropin Powder for Solution for Injection (5.8 mg - 13.8 mg)

| | |
|---|---|
| **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. 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 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:**
***(Path/File access error)***

**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 | Classification | % |
|---|---|---|---|---|
| Somatropin | 12629-01-5 | 235-735-8 | Xn;R22<br>Repr.Cat.3;R62-63<br>Xi;R43 | 44-56 |
| m-Cresol | 108-39-4 | 203-577-9 | C;R34<br>T;R24/25 | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|---|---|---|---|---|
| Dibasic Potassium Phosphate | 7758-11-4 | 231-834-5 | Not Listed | * |
| 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 | * |
| 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 with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**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.

## 5. FIRE FIGHTING MEASURES

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

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

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

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

## 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 |

**m-Cresol**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 5 ppm TWA |
| **ACGIH OELs - Notice of Intended Changes** | Listed |
| **ACGIH - Skin Absorption Designation** | Listed |
| **Australia TWA** | 22 mg/m$^3$<br>5 ppm |
| **Austria OEL - MAKs** | Listed |
| **Belgium OEL - TWA** | Listed |
| **Bulgaria OEL - TWA** | Listed |
| **Cyprus OEL - TWA** | Listed |
| **Czech Republic OEL - TWA** | Listed |
| **Denmark OEL - TWA** | Listed |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Estonia OEL - TWA** | Listed |
| **Finland OEL - TWA** | Listed |
| **France OEL - TWA** | Listed |
| **Greece OEL - TWA** | Listed |
| **Hungary OEL - TWA** | Listed |
| **Ireland OEL - TWAs** | Listed |
| **Latvia OEL - TWA** | Listed |
| **Lithuania OEL - TWA** | Listed |
| **Luxembourg OEL - TWA** | Listed |
| **Malta OEL - TWA** | Listed |
| **OSHA - Final PELS - TWAs:** | 22 mg/m$^3$<br>5 ppm |
| **OSHA - Final PELs - Skin Notations:** | Listed |
| **Poland OEL - TWA** | Listed |
| **Portugal OEL - TWA** | Listed |
| **Romania OEL - TWA** | Listed |
| **Slovenia OEL - TWA** | Listed |
| **Spain OEL - TWA** | Listed |
| **Sweden OEL - TWAs** | Listed |

**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

**Stability:** Stable under normal conditions of use.
**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

## 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)**

**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

**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

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

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

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

**m-Cresol**
Skin Irritation Rabbit Severe
Eye Irritation Rabbit Severe

**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

## 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) | *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. 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.

**m-Cresol**

**RCRA - U Series Wastes** Listed

## 14. TRANSPORT INFORMATION

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

## 15. REGULATORY INFORMATION

**EU Symbol:** Xn

## 15. REGULATORY INFORMATION

**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

**Dibasic Potassium Phosphate**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Listed |
| **Australia (AICS):** | Listed |
| **EU EINECS/ELINCS List** | 231-834-5 |

**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 |
| **EU EINECS/ELINCS List** | 200-272-2 |

**Mannitol**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Listed |

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **Australia (AICS):** | Listed |
| **REACH - Annex IV - Exemptions from the obligations of Register:** | Present |
| **EU EINECS/ELINCS 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<br>45.4 kg final RQ |
| **Inventory - United States TSCA - Sect. 8(b)** | Listed |
| **Australia (AICS):** | Listed |
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 6 |
| **EU EINECS/ELINCS List** | 203-577-9 |

**Sodium phosphate, dibasic**

| | |
|---|---|
| **CERCLA/SARA Hazardous Substances and their Reportable Quantities:** | 2270 kg final RQ<br>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.
R34 - Causes burns.
R43 - May cause sensitization by skin contact.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R24/25 - Also toxic in contact with skin and if swallowed

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

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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**End of Safety Data Sheet**