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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin</td>
<td>12629-01-5</td>
<td>235-735-8</td>
<td>5mg;12mg####</td>
</tr>
<tr>
<td>n-Cresol</td>
<td>108-39-4</td>
<td>203-577-9</td>
<td>*</td>
</tr>
<tr>
<td>Glycine</td>
<td>56-40-6</td>
<td>200-272-2</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>*</td>
</tr>
<tr>
<td>Sodium Phosphate</td>
<td>7632-05-5</td>
<td>231-558-5</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
</tbody>
</table>

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.


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/m³, Sensitizer

m-Cresol
OSHA - Final PELS - TWAs: 
= 22 mg/m³ 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/m³ 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
Molecular Formula: Mixture
Color: White
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/m³
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))
### 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 |

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Somatropin**

<table>
<thead>
<tr>
<th>Study Type, Cell Type/Organism, Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Embryo / Fetal Development</strong>&lt;br&gt;Rat, Subcutaneous 3.3 mg/kg/day NOAEL Not teratogenic&lt;br&gt;Dosage not teratogenic to rat fetuses at up to 3.3 mg/kg/day.</td>
</tr>
<tr>
<td><strong>Embryo / Fetal Development</strong>&lt;br&gt;Rabint, Intramuscular 0.3 mg/kg/day NOAEL Not Teratogenic&lt;br&gt;Chromosomal aberrations detected at the highest dose of 0.3 mg/kg/day, but not at the NOAEL dose of 0.1 mg/kg/day.</td>
</tr>
<tr>
<td><strong>Embryo / Fetal Development</strong>&lt;br&gt;Rat, Subcutaneous 3.3 mg/kg/day LOAEL Fetotoxicity&lt;br&gt;Fetal toxicity detected at the LOAEL dose of 3.3 mg/kg/day.</td>
</tr>
<tr>
<td><strong>Reproductive &amp; Fertility</strong>&lt;br&gt;Rat, Subcutaneous 0.3 mg/kg/day NOAEL Fertility&lt;br&gt;No effects at maximum dose.</td>
</tr>
<tr>
<td><strong>Peri-/Postnatal Development</strong>&lt;br&gt;Rat, Subcutaneous 3.3 mg/kg/day NOAEL No effects at maximum dose.</td>
</tr>
</tbody>
</table>

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
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 = 100 lb final RQ
and their Reportable Quantities:
= 45.4 kg final RQ
Inventory - United States TSCA - Sect. 8(b) T
Australia (AICS): Present
Standard for the Uniform Scheduling Schedule 6
for Drugs and Poisons:
EU EINECS List 203-577-9

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