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

Product Identifier

Material Name: Somatropin Powder for Solution for Injection

Trade Name: Genotropin; GENOTROPIN GoQuick; GENOTONORM
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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 3
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: Danger
Hazard Statements:
H301 - Toxic if swallowed
H312 - Harmful in contact with skin
H332 - Harmful if inhaled
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

SOMATROPIN POWDER FOR INJECT.
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
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
P330 - Rinse mouth
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P363 - Wash contaminated clothing before reuse
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin</td>
<td>12629-01-5</td>
<td>235-735-8</td>
<td>Acute Tox. 3 (H301) Acute Tox. 4 (H312, H332) Skin Sens. 1 (H317) Repr. 2 (H361fd)</td>
<td>44-56</td>
<td></td>
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<tr>
<td>m-Cresol</td>
<td>108-39-4</td>
<td>203-577-9</td>
<td>Acute Tox. 3 (H301) Skin Corr. 1B (H314)</td>
<td>&lt;1.0</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic Potassium Phosphate</td>
<td>7758-11-4</td>
<td>231-834-5</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Glycine</td>
<td>56-40-6</td>
<td>200-272-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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.
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 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

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: Formation of toxic gases is possible during heating or fire.

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

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

SOMATROPIN POWDER FOR INJECT.
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.
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

m-Cresol
ACGIH Threshold Limit Value (TWA) 20 mg/m³
ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route
Austria OEL - MAKs 5 ppm 22 mg/m³
Denmark OEL - TWA 5 ppm 22 mg/m³
Finland OEL - TWA 5 ppm 22 mg/m³
Poland OEL - TWA 22 mg/m³
Portugal OEL - TWA 5 ppm
Slovakia OEL - TWA 5 ppm 22 mg/m³
Sweden OEL - TWAs 1 ppm 4.5 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)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Lyophilized powder</th>
<th>Color:</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
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<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
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<table>
<thead>
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<th>Solvent Solubility:</th>
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<td>Water Solubility:</td>
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<tr>
<td>pH:</td>
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<tr>
<td>Melting/Freezing Point (°C):</td>
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<tr>
<td>Boiling Point (°C):</td>
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</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Somatropin
No data available

Glycine
No data available

Dibasic Potassium Phosphate
No data available

Sodium phosphate, dibasic
No data available

Mannitol
No data available

Water
No data available

m-Cresol
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
SAFETY DATA SHEET

Material Name: Somatropin Powder for Solution for Injection
Revision date: 15-Mar-2018
Version: 5.0

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

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: As a precautionary measure, keep away from strong oxidizers
- 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.

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.

Acute Toxicity: (Species, Route, End Point, Dose)

Somatropin
- Rat Oral LD50 242 mg/kg
- Rat Dermal LD50 1100mg/kg
- Rat Inhalation LC50 1h 710mg/m³
- Mouse Oral LD50 > 2000 mg/kg
- Mouse Intraperitoneal LD50 828mg/kg

Glycine
- Rat Oral LD50 7930 mg/kg
- Mouse Oral LD50 4920mg/kg

Dibasic Potassium Phosphate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 0.83mg/L
- Rabbit Dermal LD50 > 5000mg/kg

SOMATROPIN POWDER FOR INJECT.
11. TOXICOLOGICAL INFORMATION

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  2050mg/kg

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

Somatropin
Skin Irritation  Rabbit  Negative
Antigenicity- Active anaphylaxis  Guinea Pig  Positive
Antigenicity- Passive cutaneous anaphylaxis  Guinea Pig  Positive

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

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.

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.

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

Dibasic Potassium Phosphate
- 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: 231-834-5

Somatropin
- CERCLA/SARA 313 Emission reporting: Not Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>California Proposition 65</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin Powder for Injection</td>
<td>Not Listed</td>
<td>Schedule 5</td>
<td>235-735-8</td>
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<tr>
<td>Mannitol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>200-272-2</td>
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<tr>
<td>m-Cresol</td>
<td>1.0 %</td>
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<td>203-577-9</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>231-448-7</td>
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<tr>
<td>Water</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>231-791-2</td>
</tr>
</tbody>
</table>
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.
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 15-Mar-2018

Prepared by: Product Stewardship Hazard Communication

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