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

Product Identifier

Material Name: Taliglucerase alfa
Trade Name: ELELYSO
Synonyms: UPLYSO
Chemical Family: Protein

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for treatment of Gaucher’s disease

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): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous
EU Classification: EU Indication of danger: Not classified

Label Elements

Signal Word: Not required
Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

Australian Hazard Classification (NOHSC): No data available

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</td>
<td>Not Listed</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>68-04-2</td>
<td>200-675-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.

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 fire fighting 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

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. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.
Storage Temperature: 2 - 8 °C
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
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.

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

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

Hands: Wear impervious gloves as minimum protection.
Eyes: Wear safety glasses as minimum protection.
Skin: Wear impervious protective clothing when handling this compound.
Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.
SAFETY DATA SHEET

Material Name: Taliglucerase alfa
Revision date: 21-Mar-2015

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical State:</strong></td>
<td>Lyophilized powder</td>
</tr>
<tr>
<td><strong>Odor:</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Molecular Formula:</strong></td>
<td>Mixture</td>
</tr>
<tr>
<td><strong>Solvent Solubility:</strong></td>
<td>Soluble: Ethanol</td>
</tr>
<tr>
<td><strong>Water Solubility:</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Solubility:</strong></td>
<td>Soluble: Water Sodium chloride solutions</td>
</tr>
<tr>
<td><strong>pH:</strong></td>
<td>5.5-7.5</td>
</tr>
<tr>
<td><strong>Melting/Freezing Point (°C):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Boiling Point (°C):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Partition Coefficient:</strong></td>
<td>(Method, pH, Endpoint, Value)</td>
</tr>
<tr>
<td><strong>Decomposition Temperature (°C):</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Evaporation Rate (Gram/s):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor Pressure (kPa):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor Density (g/ml):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative Density:</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability:</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Autoignition Temperature (Solid) (°C):</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Flammability (Solids):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash Point (Liquid) (°C):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper Explosive Limits (Liquid) (% by Vol.):</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower Explosive Limits (Liquid) (% by Vol.):</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity:</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Chemical Stability:</strong></td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td><strong>Possibility of Hazardous Reactions</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Oxidizing Properties:</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Conditions to Avoid:</strong></td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td><strong>Incompatible Materials:</strong></td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td><strong>Hazardous Decomposition Products:</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information on Toxicological Effects</strong></td>
<td>The information included in this section describes the potential hazards of the individual ingredients.</td>
</tr>
<tr>
<td><strong>General Information:</strong></td>
<td>Common adverse effects include headache, itching sensation (pruritus), hypersensitivity reactions, nausea, flushing, swelling, and decrease in blood pressure (hypotension).</td>
</tr>
</tbody>
</table>

PZ01214
### 11. TOXICOLOGICAL INFORMATION

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>Rat</td>
<td>Oral</td>
<td>13500 mg/kg</td>
<td>55 mg/kg/day</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>22 g/kg</td>
<td></td>
</tr>
</tbody>
</table>

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taliglucerase alfa</td>
<td>39 Week(s)</td>
<td>Monkey</td>
<td>No route specified</td>
<td>27.8 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
</tbody>
</table>

**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taliglucerase alfa</td>
<td>39 Week(s)</td>
<td>Monkey</td>
<td>No route specified</td>
<td>27.8 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. 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

Canada - WHMIS: Classifications
WHMIS hazard class: None required

Polysorbate 80
- 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: Not Listed

Mannitol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 200-711-8

Sodium citrate
- 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: 200-675-3

16. OTHER INFORMATION

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

Material Name: Taliglucerase alfa
Revision date: 21-Mar-2015

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 16 - Other Information. Updated Section 11 - Toxicology Information. Updated Section 3 - Composition / Information on Ingredients.

Revision date: 21-Mar-2015
Prepared by: Product Stewardship 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