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

Product Identifier

Material Name: Liothyronine sodium tablets
Trade Name: CYTOMEL
Chemical Family: Synthetic thyroid hormone

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as synthetic hormonal agent

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

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
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

Label Elements
Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards
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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar</td>
<td>57-50-1</td>
<td>200-334-9</td>
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<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
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</tbody>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

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<tr>
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<th>%</th>
</tr>
</thead>
<tbody>
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<td>Stearic acid</td>
<td>57-11-4</td>
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<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</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:**
No data available

**Medical Conditions Aggravated by Exposure:**
None known

**Notes to Physician:**
None

Indication of the Immediate Medical Attention and Special Treatment Needed

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**
6. ACCIDENTAL RELEASE MEASURES

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
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, 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.
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.

Sugar
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³

Corn Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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).

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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
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<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
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<tr>
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</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
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<td>Solvent Solubility</td>
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<tr>
<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>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Liothyronine sodium
No data available
Gelatin
No data available
Stearic acid
No data available
Corn Starch
No data available
Calcium sulfate, dihydrate
No data available
Sugar
No data available

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
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.
Long Term: Animal studies indicate that this material may cause adverse effects on the developing fetus.
Known Clinical Effects: Clinical use of this drug has caused increased heart rate (tachycardia), ventricular arrhythmia, effects on the thyroid, headache, nervousness, and sweating.

Acute Toxicity: (Species, Route, End Point, Dose)
11. TOXICOLOGICAL INFORMATION

Liothyronine sodium
Rat Oral LD50 7500 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000 mg/kg

Sugar
Rat Oral LD50 29700 mg/kg
Mouse Oral LD50 14000mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Stearic acid
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Mild

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

Liothyronine sodium
3 Month(s) Rat Oral 6 µg/kg/day NOAEL No effects at maximum dose
3 Month(s) Rat Oral 6 µg/kg/day NOAEL No effects at maximum dose

Stearic acid
30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

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

Liothyronine sodium
Embryo / Fetal Development Mouse Oral Dose not specified Fetotoxicity, Not teratogenic

Stearic acid
In Vitro Bacterial Mutagenicity (Ames) Salmonella Negative

Unscheduled DNA Synthesis E. coli Negative

Stearic acid
26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOAEL Tumors

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 thoroughly 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

Sugar
- 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: 200-334-9

Corn Starch
- 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
15. REGULATORY INFORMATION

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<td>Present</td>
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</tbody>
</table>

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification.

Revision date: 16-May-2016


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