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

Material Name: Metoclopramide Capsules
Trade Name: Gastrosil; Gastromax
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as gastric motility regulator.

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

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>Metoclopramide</td>
<td>364-62-5</td>
<td>206-662-9</td>
<td>30mg***</td>
</tr>
<tr>
<td>Maize starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylcellulose</td>
<td>9004-57-3</td>
<td>Not listed</td>
<td></td>
</tr>
<tr>
<td>Erythrosine (CI 45430)</td>
<td>16423-68-0</td>
<td>240-474-8</td>
<td>*</td>
</tr>
<tr>
<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>*</td>
</tr>
<tr>
<td>Shellac</td>
<td>9000-59-3</td>
<td>232-549-9</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Orange, yellow capsules
Signal Word: WARNING

Statement of Hazard:
May be harmful if swallowed.
May cause central nervous system effects

Additional Hazard Information:
Short Term: Effects of breathing dust are not known. Avoid inhaling this material.
Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Hypersensitivity reactions may also occur in susceptible individuals.

EU Indication of danger: Harmful

EU Hazard Symbols:

EU Risk Phrases: R22 - Harmful if swallowed.

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 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.

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: Not applicable

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid generating airborne dust.

Storage Conditions: Store at controlled room temperature.

Storage Temperature: (15-25°C)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Maize starch
- OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
  = 5 mg/m³ TWA
- ACGIH Threshold Limit Value (TWA)
  = 10 mg/m³ TWA
- Australia TWA
  = 10 mg/m³ TWA

Sucrose
- OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
  = 5 mg/m³ TWA
- ACGIH Threshold Limit Value (TWA)
  = 10 mg/m³ TWA
- Australia TWA
  = 10 mg/m³ TWA

Talc (non-asbestiform)
- OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA
  = 2 mg/m³ TWA
- ACGIH Threshold Limit Value (TWA)
  = 2.5 mg/m³ TWA containing no asbestos fibers
- Australia TWA
  = 2.5 mg/m³ TWA containing no asbestos fibers

Titanium dioxide
- OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
- ACGIH Threshold Limit Value (TWA)
  = 10 mg/m³ TWA
- Australia TWA
  = 10 mg/m³ TWA

Colloidal silicon dioxide
- OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO2) mg/m³ TWA
  = 20 mppcf TWA
- Australia TWA
  = 2 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
<th>Color:</th>
<th>Yellow orange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

- Stability: Stable under normal conditions of use.
- Conditions to Avoid: None for the normal use of this material.
- Incompatible Materials: None known.

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)**

- **Talc (non-asbestiform)**
  - Rat Oral LD50 > 1600 mg/kg

- **Sucrose**
  - Rat Oral LD50 29.7 g/kg

- **Metoclopramide**
  - Rat Oral LD50 750 mg/kg
  - Mouse Oral LD50 270 mg/kg
  - Rat Intraperitoneal LD 50 114 mg/kg

- **Titanium dioxide**
  - Rat Oral LD50 > 7500 mg/kg
  - Rat Subcutaneous LD 50 50 mg/kg

- **Erythrosine (CI 45430)**
  - Rat Oral LD50 1840 mg/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.

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

- **Metoclopramide**
  - Embryo / Fetal Development Rat Oral 10 mg/kg/day NOEL Not teratogenic
  - Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOEL Not Teratogenic
  - Embryo / Fetal Development Mouse Oral 10 mg/kg/day NOEL Not Teratogenic
  - Embryo / Fetal Development Rabbit Intravenous 10 mg/kg NOEL Not Teratogenic

**Carcinogen Status:** See below

**Colloidal silicon dioxide**

- **IARC:** Group 3
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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
EU Risk Phrases: R22 - Harmful if swallowed.
EU Safety Phrases: S22 - Do not breathe dust.

OSHA Label:
WARNING
May be harmful if swallowed.
May cause central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class: D2b toxic materials
Metoclopramide

Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
EU EINECS List: 206-662-9

Maize starch
Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present
EU EINECS List: 232-679-6

Sucrose
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 200-334-9

Talc (non-asbestiform)
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 238-877-9

Titanium dioxide
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 236-675-5

Colloidal silicon dioxide
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 231-545-4

Ethylcellulose
Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present

Erythrosine (CI 45430)
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 240-474-8

Ferric oxide yellow
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 257-098-5

Gelatin
Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present
EU EINECS List: 232-554-6

Shellac
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List 232-549-9

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

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

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End of Safety Data Sheet