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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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+00 44 (0)1304 616161

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

Material Name: Micronized Colestipol Hydrochloride Tablets

Trade Name: COLESTID; LESTID
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of high cholesterol (hyperlipidemia).

2. HAZARDS IDENTIFICATION

Appearance: Light yellow tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Not acutely toxic. Not expected to cause skin irritation (based on components).

Known Clinical Effects: Adverse effects most commonly reported in clinical use include gastrointestinal disturbances, constipation, abdominal pain, flatulence, heartburn, diarrhea, nausea, and vomiting.

EU Classification
EU Indication of danger: Not classified


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.

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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colestipol Hydrochloride</td>
<td>37296-80-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>88</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ingredient CAS Number EU EINECS/ELINCS List EU Classification %
Cellulose acetate phthalate 9004-38-0 Not Listed Not Listed *
Glycerol triacetate 102-76-1 203-051-9 Not Listed *
Carnauba wax 8015-86-9 232-399-4 Not Listed *
Povidone 9003-39-8 Not Listed Not Listed *
Hydroxypropyl methylcellulose 9004-65-3 Not Listed Not Listed *

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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.

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.

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:** 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). 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.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

**Colestipol Hydrochloride**

<table>
<thead>
<tr>
<th>Member State</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
</tbody>
</table>

**Colloidal silicon dioxide**

<table>
<thead>
<tr>
<th>Member State</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>Germany OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>2.4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
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</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>Listed</td>
</tr>
</tbody>
</table>

**Magnesium stearate**

<table>
<thead>
<tr>
<th>Member State</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

**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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**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 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>Tablets</th>
<th>Color:</th>
<th>Light yellow</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

Chemical Stability: Stable under normal conditions of use.
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.

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)

**Colestipol Hydrochloride**
- Rat Oral LD50 >1000 mg/kg
- Mouse Oral LD50 >1000 mg/kg
- Rat Intraperitoneal LD50 >4000 mg/kg
- Mouse Intraperitoneal LD50 >4000 mg/kg

**Povidone**
- Rat Oral LD50 100 g/kg

**Hydroxypropyl methylcellulose**
- Rat Oral LD50 > 10,000 mg/kg

**Magnesium stearate**
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

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.

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

**Colestipol Hydrochloride**
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Non-irritating

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

**Colestipol Hydrochloride**
- 1 Month(s) Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose
- 14 Day(s) Rabbit Oral 4000 mg/kg/day NOAEL No effects at maximum dose
- 1 Month(s) Dog Oral 3000 mg/kg/day LOAEL None identified
SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets
Revision date: 23-Oct-2013

11. TOXICOLOGICAL INFORMATION

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

Colestipol Hydrochloride
Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 1000 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Colestipol Hydrochloride
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Colestipol Hydrochloride
18 Month(s) Rat Oral 2000 mg/kg/day NOAEL Not carcinogenic

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

Povidone
IARC: Group 3 (Not Classifiable)

Colloidal silicon dioxide
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

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**

**EU Indication of danger:**  Not classified

**OSHA Label:**
Non-hazardous in accordance with international standards for workplace safety.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

<table>
<thead>
<tr>
<th>Material Name</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colestipol Hydrochloride</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose acetate phthalate</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerol triacetate</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carnauba wax</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Ingredient</th>
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<th>Inventory - United States TSCA - Sect. 8(b)</th>
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</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Australia (AICS):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Standard for the Uniform Scheduling</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>not listed</td>
<td>Schedule 4</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 7 - Handling and Storage. Updated Section 4 - First Aid Measures.

**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**