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

Product Identifier

Material Name: Colestipol Hydrochloride for Oral Suspension
Trade Name: COLESTID
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product for the treatment of high cholesterol (hyperlipidemia).

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

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

Label Elements
Signal Word: Warning
Hazard Statements: May form combustible dust concentrations in air

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

Hazardous

FLAVORED COLESTID
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>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colestipol Hydrochloride</td>
<td>37296-80-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>67</td>
</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>Beta Carotene</td>
<td>7235-40-7</td>
<td>230-636-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Flavor blend</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylcellulose</td>
<td>9004-67-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Veltol (maltol FCC)</td>
<td>118-71-8</td>
<td>204-271-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</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>
<tr>
<td>Aspartame</td>
<td>22839-47-0</td>
<td>245-261-3</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

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.
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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid generating airborne dust. 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.

Glycerin, USP

Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Czech Republic OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
Finland OEL - TWA 20 mg/m³
France OEL - TWA 10 mg/m³
Germany (DFG) - MAK 200 mg/m³
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 50 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Colestipol Hydrochloride**

**Pfizer OEL TWA-8 Hr:** 3000µg/m³

**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

**Physical State:** Granules

**Odor:** No data available.

**Molecular Formula:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available.

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Beta Carotene**

No data available

**Flavor blend**

No data available

**Velto (maltol FCC)**

No data available

**Mannitol**

No data available

**Methylcellulose**

No data available

**Colestipol Hydrochloride**

Predicted Log P -1.32

**Aspartame**

No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

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.

**Short Term:** May cause irritation (based on components).

**Long Term:** Animal studies indicate that this material may cause adverse effects on the endocrine system.

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

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

**Veltol (maltol FCC)**

- **Rat** Oral LD50 1410 mg/kg
- **Mouse** Oral LD50 550 mg/kg

**Mannitol**

- **Rat** Oral LD50 13500 mg/kg
- **Mouse** Oral LD50 22 g/kg

**Colestipol Hydrochloride**

- **Rat** Oral LD50 >1000 mg/kg
- **Mouse** Oral LD50 >1000 mg/kg

FLAVORED COLESTID
11. TOXICOLOGICAL INFORMATION

**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)

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

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

**Genetic Toxicity:** (Study Type, Cell Type/Organism, Result)

**Carcinogenicity:** (Duration, Species, Route, Dose, End Point, Effect(s))

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

---

**Material Name:** Colestipol Hydrochloride for Oral Suspension

**Revision date:** 11-Jan-2019

**Version:** 3.1

---

**Glycerin, USP**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Eye Irritation**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
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</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Colestipol Hydrochloride**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Skin Irritation**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Embryo / Fetal Development**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2000 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
<td></td>
</tr>
</tbody>
</table>

---

**Bacterial Mutagenicity (Ames)**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella, E. coli</td>
<td>Negative</td>
</tr>
</tbody>
</table>
12. ECOLOGICAL INFORMATION

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

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water Flea)</td>
<td>EC50</td>
<td>24 Hours</td>
<td>&gt;500 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Predicted Log P</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Colestipol Hydrochloride</em></td>
<td>-1.32</td>
</tr>
</tbody>
</table>

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
## 15. REGULATORY INFORMATION

### Glycerin, USP
- **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 V - Exemptions from the obligations of Register**: Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bio accumulative, and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
- **EU EINECS/ELINCS List**: 200-289-5

### Beta Carotene
- **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**: 230-636-6

### Flavor blend
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed

### Methylcellulose
- **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

### Veltol (maltol FCC)
- **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**: 204-271-8

### Colestipol Hydrochloride
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed

### Citric acid, anhydrous
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance/Preparation</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>Present</td>
<td>201-069-1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance/Preparation</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance/Preparation</th>
<th>CERCLA/SARA 313 Emission reporting</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>Aspartame</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>245-261-3</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 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 11-Jan-2019

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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