



# SAFETY DATA SHEET

Revision date: 15-Apr-2015

Version: 3.0

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## 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

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** May form combustible dust concentrations in air

### Other Hazards

No data available

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

### 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.

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*
Colestipol Hydrochloride	37296-80-3	Not Listed	Not Listed	Not Listed	67

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Beta Carotene	7235-40-7	230-636-6	Not Listed	Not Listed	*
Flavor blend	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Methylcellulose	9004-67-5	Not Listed	Not Listed	Not Listed	*
Veltol (maltol FCC)	118-71-8	204-271-8	Not Listed	Not Listed	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	Not Listed	*
Aspartame	22839-47-0	245-261-3	Not Listed	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	Not Listed	*

#### 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

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	No data available
<b>Medical Conditions Aggravated by Exposure:</b>	None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

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**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

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/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	20 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	50 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs 50 mg/m<sup>3</sup>

Colestipol Hydrochloride  
Pfizer OEL TWA-8 Hr: 3000µg/m<sup>3</sup>

#### 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).

##### 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

<b>Physical State:</b>	Granules	<b>Color:</b>	Light orange
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

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

**Beta Carotene**  
No data available

**Flavor blend**  
No data available

**Veltol (maltol FCC)**  
No data available

**Mannitol**  
No data available

**Methylcellulose**  
No data available

**Colestipol Hydrochloride**  
Predicted Log P -1.32

**Aspartame**  
No data available

**Glycerin, USP**  
No data available

**Decomposition Temperature (°C):** No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available

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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 550mg/kg

#### Mannitol

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

#### 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

#### Glycerin, USP

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 > 21.9 g/kg

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### 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)

##### **Colestipol Hydrochloride**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Non-irritating

##### **Glycerin, USP**

Eye Irritation Rabbit Mild

#### 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
18 Month(s)	Rat	Oral	2000 mg/kg/day	NOAEL	No effects at maximum dose
1 Year(s)	Dog	Oral	500 mg/kg/day	LOAEL	None identified

#### 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.

### 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)

##### **Glycerin, USP**

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*Oncorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L  
*Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

**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)**  
**Colestipol Hydrochloride**  
Predicted Log P -1.32

**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

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.

**Glycerin, USP**

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### 15. REGULATORY INFORMATION

<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>REACH - Annex V - Exemptions from the obligations of Register:</b>	Not Listed Not Listed Present Present 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, bioaccumulative, and toxic or very persistent and very bioaccumulative 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
<b>EU EINECS/ELINCS List</b>	200-289-5
<b>Beta Carotene</b>	
<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>EU EINECS/ELINCS List</b>	Not Listed Not Listed Present Present 230-636-6
<b>Flavor blend</b>	
<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>EU EINECS/ELINCS List</b>	Not Listed Not Listed Not Listed
<b>Methylcellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>EU EINECS/ELINCS List</b>	Not Listed Not Listed Present Present Not Listed
<b>Veltol (maltol FCC)</b>	
<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>EU EINECS/ELINCS List</b>	Not Listed Not Listed Present Present 204-271-8
<b>Colestipol Hydrochloride</b>	
<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>EU EINECS/ELINCS List</b>	Not Listed Not Listed Not Listed
<b>Citric acid, anhydrous</b>	
<b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>EU EINECS/ELINCS List</b>	Not Listed Not Listed Present Present 201-069-1



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### 15. REGULATORY INFORMATION

#### Aspartame

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	245-261-3

#### 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

### 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 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date:** 15-Apr-2015

Product Stewardship Hazard Communication

**Prepared by:** 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**