



# SAFETY DATA SHEET

Revision date: 11-Jan-2019

Version: 3.1

Page 1 of 9

## 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:  
International CHEMTREC (24 hours): +1-703-527-3887

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

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 2 of 9  
Version: 3.1

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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

**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 CO<sub>2</sub>, 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.

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 3 of 9  
Version: 3.1

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all firefighting 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. 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/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	200 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>
Switzerland OEL - TWAs	50 mg/m <sup>3</sup>

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 4 of 9  
Version: 3.1

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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). 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

#### Color:

Light orange

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

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

#### Veltol (maltol FCC)

No data available

#### Mannitol

No data available

#### Methylcellulose

No data available

#### Colestipol Hydrochloride

Predicted Log P -1.32

#### Aspartame

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 5 of 9  
Version: 3.1

### 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

#### Glycerin, USP

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 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

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 6 of 9  
Version: 3.1

### 11. TOXICOLOGICAL INFORMATION

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

**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.

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 7 of 9  
Version: 3.1

### 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**

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	50 mg/L
<i>Daphnia magna</i> (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**

## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 8 of 9  
Version: 3.1

### 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



## SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension  
Revision date: 11-Jan-2019

Page 9 of 9  
Version: 3.1

### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

#### 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

#### 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

### 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  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**