



# MATERIAL SAFETY DATA SHEET

Revision date: 29-Nov-2007

Version: 1.4

Page 1 of 7

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

**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**  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

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

### 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 Indication of danger:** Not classified

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Colestipol Hydrochloride	37296-80-3	Not listed	Not Listed	88
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*

# MATERIAL SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets  
Revision date: 29-Nov-2007

Page 2 of 7  
Version: 1.4

Ingredient	CAS Number	EU EINECS/ELINCS List	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	*
Hypromellose	9004-65-3	Not listed	Not Listed	*
Povidone	9003-39-8	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.

## 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).

# MATERIAL SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets  
Revision date: 29-Nov-2007

Page 3 of 7  
Version: 1.4

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  
Pfizer OEL TWA-8 Hr:

3000 $\mu$ g/m<sup>3</sup>

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m <sup>3</sup> TWA	
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m <sup>3</sup> IPRV	
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	

Colloidal silicon dioxide

Australia TWA	= 2 mg/m <sup>3</sup> TWA	
Austria OEL - MAKs	= 4 mg/m <sup>3</sup> MAK	
Czech Republic OEL - TWA	= 0.1 mg/m <sup>3</sup> TWA	
	= 4.0 mg/m <sup>3</sup> TWA	
Estonia OEL - TWA	= 2 mg/m <sup>3</sup> TWA	
Germany - TRGS 900 - TWAs	= 4 mg/m <sup>3</sup> TWA	
Ireland OEL - TWAs	= 2.4 mg/m <sup>3</sup> TWA	
	= 6 mg/m <sup>3</sup> TWA	
Latvia OEL - TWA	= 1 mg/m <sup>3</sup> TWA	containing more than 70% SiO <sub>2</sub> (quartz)
	= 2 mg/m <sup>3</sup> TWA	containing 10-70% SiO <sub>2</sub> (granite, mica)
	= 4 mg/m <sup>3</sup> TWA	containing 2-10% SiO <sub>2</sub> (copper sulfate ores)
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(%) SiO <sub>2</sub> ) mg/m <sup>3</sup> TWA	
	= 20 mppcf TWA	
Slovakia OEL - TWA	= 4.0 mg/m <sup>3</sup> TWA	
Slovenia OEL - TWA	= 4 mg/m <sup>3</sup> TWA	

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:

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:

Physical State: Tablets Color: Light yellow

# MATERIAL SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets  
Revision date: 29-Nov-2007

Page 4 of 7  
Version: 1.4

Molecular Formula: Mixture Molecular Weight: Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known  
**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

#### **Hypromellose**

Rat Oral LD50 > 10,000 mg/kg

#### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

**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  
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))

## MATERIAL SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets  
Revision date: 29-Nov-2007

Page 5 of 7  
Version: 1.4

### 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

#### 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. Member State specific and Community specific provisions must be considered.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

#### EU Indication of danger:

Not classified

# MATERIAL SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets  
Revision date: 29-Nov-2007

Page 6 of 7  
Version: 1.4

## 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.

### Cellulose acetate phthalate

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

### Glycerol triacetate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9

### Carnauba wax

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-399-4

### Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

### Povidone

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

### Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 EEC No. 418-260-2

## MATERIAL SAFETY DATA SHEET

Material Name: Micronized Colestipol Hydrochloride Tablets  
Revision date: 29-Nov-2007

Page 7 of 7  
Version: 1.4

---

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties.

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

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**