



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.2

Page 1 of 5

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

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

Material Name: Colestipol Hydrochloride for Oral Suspension

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Silicon dioxide, NF	7631-86-9	231-545-4	*
Colestipol Hydrochloride	37296-80-3	Not listed	5 gm

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

3. HAZARDS IDENTIFICATION

Appearance: Light yellow Granules

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

Additional Hazard Information:

Short Term: Not acutely toxic (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.

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.

4. FIRST AID MEASURES

MATERIAL SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension
Revision date: 15-Dec-2006

Page 2 of 5
Version: 1.2

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

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:	Avoid generating airborne dust. Avoid contact with eyes, skin and clothing.
Storage Conditions:	Store at controlled room temperature. Protect from moisture.
Storage Temperature:	20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Silicon dioxide, NF	
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO ₂) mg/m ³ TWA = 20 mppcf TWA
Australia TWA	= 2 mg/m ³ TWA

Colestipol Hydrochloride	
Pfizer OEL TWA-8 Hr:	3mg/m ³
The exposure limit(s) listed for solid components are only relevant if dust may be generated.	

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
------------------------------	--

MATERIAL SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension
Revision date: 15-Dec-2006

Page 3 of 5
Version: 1.2

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
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:	Granules	Color:	Light yellow
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to moisture
Incompatible Materials: None

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)

Silicon dioxide, NF

Rat Oral LD50 10 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

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 No effect

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 Endocrine system

18 Month(s) Rat Oral 2000 mg/kg/day NOAEL No effects at maximum dose

MATERIAL SAFETY DATA SHEET

Material Name: Colestipol Hydrochloride for Oral Suspension
Revision date: 15-Dec-2006

Page 4 of 5
Version: 1.2

1 Year(s) Dog Oral 500 mg/kg/day LOAEL Endocrine system

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

Silicon dioxide, NF

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.

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: Colestipol Hydrochloride for Oral Suspension
Revision date: 15-Dec-2006

Page 5 of 5
Version: 1.2

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.

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

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.

End of Safety Data Sheet