



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.2

Page 1 of 6

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

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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Colestipol Hydrochloride for Oral Suspension

Trade Name: Flavored 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	%
Colestipol Hydrochloride	37296-80-3	Not listed	67
Glycerin, USP	56-81-5	200-289-5	*

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

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

3. HAZARDS IDENTIFICATION

Appearance: Light orange Granules

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

Additional Hazard Information:

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.

EU Indication of danger: Not classified

MATERIAL SAFETY DATA SHEET

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

Page 2 of 6
Version: 1.2

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

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

MATERIAL SAFETY DATA SHEET

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

Page 3 of 6
Version: 1.2

Colestipol Hydrochloride

Pfizer OEL TWA-8 Hr: 3mg/m³

Glycerin, USP

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

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.

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 orange
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)

Citric acid

Rat Oral LD50 3000 mg/kg

Veltol (maltol FCC)

Rat Oral LD50 1410 mg/kg

Mouse Oral LD50 550 mg/kg

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

Colestipol Hydrochloride

MATERIAL SAFETY DATA SHEET

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

Page 4 of 6
Version: 1.2

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/m³
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)

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Colestipol Hydrochloride

Eye Irritation Rabbit Mild
Skin Irritation Rabbit No effect

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 Endocrine system
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 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.

MATERIAL SAFETY DATA SHEET

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

Page 5 of 6
Version: 1.2

12. ECOLOGICAL INFORMATION

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

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

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LC-50 96 Hours 50 mg/L

Daphnia Magna (Water Flea) EC-50 24 Hours >500 mg/L

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

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

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.

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

Beta Carotene

MATERIAL SAFETY DATA SHEET

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

Page 6 of 6
Version: 1.2

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	230-636-6
Citric acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1
Mannitol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8
Methylcellulose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Veltol (maltol FCC)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-271-8
Aspartame	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	245-261-3

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet