

SAFETY DATA SHEET

Colesevelam Hydrochloride, 625mg Tablets

DATE INITIAL PREPARATION: July 1, 2009

DATE LAST REVISED: March 30, 2015

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT IDENTIFIER:

Product name: Colesevelam Hydrochloride, 625 mg Tablets and Welchol[®], 625 mg Tablets

Active ingredient: Colesevelam Hydrochloride

RELEVANT IDENTIFIED USES OF SUBSTANCE OR MIXTURE:

Product use: Colesevelam Hydrochloride, 625 mg Tablets and Welchol[®], 625 mg Tablets is a bile acid binding polymer that reduces LDL cholesterol levels in humans. It has been approved for treatment of hyperlipidemia by the US FDA and has demonstrated appropriate safety and efficacy for use of treating elevated LDL cholesterol.

SUPPLIER

Company: Daiichi Sankyo, Inc.

Address: 2 Hilton Court
Parsippany, NJ 07054

Phone Number: 877- 437-7763

Emergency Phone Number: 877- 437-7763

COMMENTS: To the best of our knowledge, this Safety Data Sheet conforms to the requirements of U.S. Occupational Safety and Health Administration (OSHA) Title 29 Code of Federal Regulations Section 1910.1200 (29 CFR 1910.1200).

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Classification of the substance or mixture according to the U.S. Hazard Communication Standard

** These hazards apply to the powder form of the raw substance, Colesevelam hydrochloride.*

Skin Irrit. 2 H315 **Causes skin irritation.**

Eye Irrit. 2A H319 **Causes serious eye irritation.**

STOT SE 3 H335 **May cause respiratory irritation.**

Label elements

GHS label elements The substance is classified and labeled according to the Globally Harmonized System (GHS).

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Hazard pictogram

Signal word: **Warning**

Hazard statements: H315 **Causes skin irritation.**
 H319 **Causes serious eye irritation.**
 H335 **May cause respiratory irritation.**

Precautionary statements:

P280 Wear protective gloves.
 P280 Wear eye protection / face protection.
 P261 Avoid breathing dust/fume/gas/mist/vapors/spray
 P264 Wash thoroughly after handling.
 P271 Use only outdoors or in a well-ventilated area.
 P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P302+P352 If on skin: Wash with plenty of water.
 P312 Call a poison center/doctor if you feel unwell.
 P321 Specific treatment (see on this label).
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P405 Store locked up.
 P403+P233 Store in a well-ventilated place. Keep container tightly closed.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

NFPA RATINGS

Health	1
Fire	0
Reactivity	0
Personal Protection	X

Key:
 0=Insignificant
 1=Slight
 2=Moderate
 3=High
 4=Extreme
 X=Determined by User

HMIS-CODE

Health	1
Fire	0
Reactivity	0

TARGET ORGANS: None.

ROUTES OF ENTRY: Inhalation, Skin contact, Eye contact.

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POTENTIAL HEALTH EFFECTS/SYMPTOMS OF EXPOSURE**EYE CONTACT:** Prolonged or repeated contact may cause irritation in some individuals.**SKIN CONTACT:** Prolonged or repeated contact may cause irritation in some individuals.**INGESTION:** Not toxic by ingestion.**INHALATION:** Prolonged or repeated inhalation of dust may cause irritation in some individuals.**COMMENTS:** For detailed toxicological information see Section 11.**3. COMPOSITION / INFORMATION ON INGREDIENTS**

Chemical Name	Synonyms	Wt %	CAS #
Colesevelam hydrochloride	1-Hexanaminium, N,N,N-trimethyl-6-(2-propen-1-ylamino)-, chloride (1:1), polymer with 2-(chloromethyl)oxirane, 2-propen-1-amine and N-2-propen-1-yl-1-decanamine, hydrochloride CholestaGel	70.00%	182815-44-7
Microcrystalline cellulose	Not available	16.00%	9004-34-6
Pharmaceutical excipients	Not available	14.00%	Not available

4. FIRST AID MEASURES**NOTE:** These first aid measures apply only to accidental or intentional misuse of this product.**EYES:** Immediately flush eyes with water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.**SKIN:** If skin irritation develops, or other symptoms occur, discontinue use and wash skin with water. Seek medical attention if symptoms persist.**INGESTION:** Obtain medical attention if over 5 grams are ingested. If abdominal pains develop, seek medical attention.**INHALATION:** If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist.**5. FIRE FIGHTING MEASURES****FIRE FIGHTING PROCEDURES****FIRE FIGHTING EQUIPMENT:** Wear full protective clothing and self-contained breathing apparatus.

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EXTINGUISHING MEDIA: Carbon dioxide (CO₂), extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

HAZARDOUS DECOMPOSITION PRODUCTS: Not flammable. In fire conditions, carbon monoxide (CO) and nitrogen oxides (NO_x) may be released. Excessive dust may create flammable or explosive environments.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

- Do not breathe dust.
- Wear protective clothing.
- Avoid contact with eyes and skin.
- Use respiratory protective device against the effects of fumes/dust/aerosol.
- Avoid formation of dust.

SPILL: Minimize entry of material into sewers and drainage systems.

METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP: This product may be collected by scooping into a pan, paper towel or other absorbent material. Transfer into suitable containers for recovery or disposal.

7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING:

- Empty containers must not be used for other products.
- Contaminated protective equipment should be cleaned before taking it off.
- Ensure good ventilation/exhaustion at the workplace.
- Fill only in dedicated and assigned containers.
- Keep containers tightly sealed.

STORAGE: Keep this and all drugs out of the reach of children. Keep container tightly closed when not in use. Store in original containers. Protect from extremes of cold. Storage area should be: -cool -dry - well ventilated - out of direct sunlight.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION**EXPOSURE GUIDELINES**

Chemical	ACGIH (TLV®)	NIOSH (REL)	OSHA (PEL)
Colesevelam hydrochloride	N.E.	N.E.	N.E.
Microcrystalline cellulose	10 mg/m ³ (inhalable fraction of dust)	15 mg/m ³ (total dust)	15 mg/m ³ (total dust)
	3 mg/m ³ (respirable fraction of dust)	5 mg/m ³ (respirable fraction of dust)	5 mg/m ³ (respirable fraction of dust)
mg/m ³ = micrograms per cubic meter N.E. = Not Established			

ENGINEERING CONTROLS:

Good general room ventilation is expected to be adequate to control airborne levels.

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Not normally required. However, care should be taken to avoid accidental exposure. The use of safety glasses with side shields is recommended in situations where repeated contact with the eyes may occur.

SKIN: Chemical resistant gloves.

RESPIRATORY: Not normally required. Respiratory protection if there is a risk of exposure to high vapor concentrations.

If respirators are used the respiratory protection program needs to meet requirements of 29 CFR 1910.134 (or equivalent in countries other than the United States).

PROTECTIVE CLOTHING: Normal work wear.

9. PHYSICAL AND CHEMICAL PROPERTIES**APPEARANCE**

PHYSICAL STATE: Solid tablet

COLOR: Off-white with imprint

ODOR: Odorless, dust may have an amine-like odor

ODOR THRESHOLD: Not available.

pH: 3-4 (as slurry in water).

MELTING POINT: Not available.

FREEZING POINT: Not available.

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INITIAL BOILING POINT: Not available.**BOILING RANGE:** Not available.**FLASH POINT:** Not available.**EVAPORATION RATE:** Not available.**FLAMMABILITY:** Not available.**UPPER EXPLOSIVE LIMIT:** Not available.**LOWER EXPLOSIVE LIMIT:** Not available.**VAPOR PRESSURE:** Not available.**VAPOR DENSITY:** Not available.**RELATIVE DENSITY:** Not available.**SOLUBILITY:** Insoluble**PARTITION COEFFICIENT: n-octanol/water;** Not available.**AUTO-IGNITION TEMPERATURE:** Not available.**DECOMPOSITION TEMPERATURE:** Not available.**VISCOSITY:** Not available.

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable under normal conditions.**REACTIVITY:** Not available.**POSSIBILITY OF HAZARDOUS REACTIONS, POLYMERIZATION:** Will not occur.**CONDITIONS TO AVOID:** Heat, high temperatures.**INCOMPATIBLE MATERIALS:** Strong bases.**HAZARDOUS DECOMPOSITION PRODUCTS:** Oxides of carbon; oxides of nitrogen; hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

ACUTE EFFECTS

EYES: Not Available**INHALATION TC_{Lo}:** Not Available**DERMAL LD₅₀:** Not Available.**ORAL LD₅₀:** Rat > 3,000 mg/kg.

POTENTIAL HEALTH EFFECTS

EYE CONTACT: Prolonged or repeated contact may cause irritation in some individuals.**SKIN CONTACT:** Prolonged or repeated contact may cause irritation in some individuals.

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INGESTION: Not toxic by ingestion.

INHALATION: Prolonged or repeated contact may cause irritation in some individuals.

SUBCHRONIC HEALTH EFFECTS:

Oral: Dog, Beagle- 90 day MTD>2 g/kg/day (MTD is the maximum tolerated dose).

Oral: Rat, Sprague- Dawley- 90 day MTD> 3g/kg/day (>50x recommended human dose).

CHRONIC HEALTH EFFECTS: Not known

CARCINOGENICITY:

Oral: Rat, Sprague-Dawley- 104-week, no significant increase in tumors at 3 g/kg/day (50x recommended human dose).

NTP: Substance is not listed.

IARC: Substance is not listed.

OSHA: Substance is not listed.

REPRODUCTIVE/TERATOGENIC EFFECTS:

Oral: Rats- no observed effects up to 3 g/kg/day.

MUTAGENICITY:

Not available.

GENOTOXICITY:

Ames test—negative

Mammalian chromosomal aberration test—negative

12. ECOTOXICOLOGICAL INFORMATION

AQUATIC TOXICITY

Toxicity for fish: LC₅₀ (24h, 48h, 72h, and 96h) >100mg/l (*Zebra fish*).

Toxicity for algae: EC₅₀ (72h) >201 mg/l (*Selenastrum capricornutum*)

Toxicity for daphnia: EC₅₀ (24 h and 48h) >100 mg/l (*Daphnia magna*).

PERSISTENCE AND DEGRADABILITY

Not readily biodegradable.

BIOACCUMULATIVE POTENTIAL

No relevant studies identified.

MOBILITY IN SOIL

No relevant studies identified.

OTHER ADVERSE EFFECTS

Not determined.

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13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with all applicable local and national regulations.

14. TRANSPORT INFORMATION

DOT CFR 172.101 Data	Not Regulated.
UN Proper Shipping Name	Not Regulated.
UN Class	None.
UN Number	None.
UN Packaging Group	None.
Transport Hazard Class	Not Available.
Environmental Hazards	Not Available.
Transport in Bulk	Not Available.
Special Precautions	Not Available.

15. REGULATORY INFORMATION**TSCA Listing**

This product does not contain ingredients that are listed on or exempt from listing on the EPA Toxic Substance Control Act Chemical Inventory.

EINECS Listing

All ingredients in this product are listed on the European Inventory of Existing Commercial Chemical Substances (EINECS) or the European List of New Chemical Substances (ELINCS) or are exempt from listing.

WHMIS Classification

All ingredients are exempt from listing by WHMIS.

MA Right To Know Law

This product does not contain any chemicals listed on the Massachusetts Right To Know Substance List.

PA Right To Know Law

This product does not contain any chemicals on the Pennsylvania Hazardous Substance List.

NJ Right To Know Law

This product does not contain any chemicals on the New Jersey Workplace Hazardous Substance List.

California Proposition 65

This product does not contain materials which the State of California has found to cause cancer, birth defects or other reproductive harm.

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SARA Title III Sect. 302 (EHS)

This product does not contain any chemicals subject to SARA Title III Section 302.

SARA Title III Sect. 304

This product does not contain any chemicals subject to SARA Title III Section 304.

SARA Title III Sect. 311/312 Categorization

This product does not contain any chemicals subject to SARA Title III Section 311/312.

SARA Title Sect. 313

This product does not contain a chemical that is listed in Section 313 at or above de minimis concentrations.

16. OTHER INFORMATION**NFPA Ratings**

NFPA Code for Flammability: 0

NFPA Code for Health: 1

NFPA Code for Reactivity: 0

NFPA Code for Special Hazards: 0

Abbreviations

N/A: Denotes no applicable information found or available

CAS #: Chemical Abstracts Service Number

ACGIH: American Conference of Governmental Industrial Hygienists

OSHA: Occupational Safety and Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit

NTP: National Toxicology Program

IARC: International Agency for Research on Cancer

R: Risk

S: Safety

EC₅₀: Effective Concentration 50%

LC 50: Lethal Concentration 50%

LD 50: Lethal Dose 50%

BOD: Biological Oxygen Demand

KoC: Soil Organic Carbon Partition Coefficient

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