

# SAFETY DATA SHEET

## Colesevelam Hydrochloride Powder for Oral Suspension

DATE INITIAL PREPARATION: September 15, 2009

DATE LAST REVISED: March 30, 2015

### 1. PRODUCT AND COMPANY IDENTIFICATION

#### PRODUCT IDENTIFIER:

Product name: Colesevelam hydrochloride Powder for Oral Suspension and Welchol® Powder for Oral Suspension

Active ingredient: Colesevelam hydrochloride

#### RELEVANT IDENTIFIED USES OF SUBSTANCE OR MIXTURE:

Product use: Colesevelam hydrochloride Powder for Oral Suspension and Welchol® Powder for Oral Suspension 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 US 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 pictograms



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.

Other hazards

**Combustible material****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:** Skin, eyes, mucous membranes, respiratory tract, and gastrointestinal tract.**ROUTE OF ENTRY:** Ingestion or inhalation of dust

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**POTENTIAL HEALTH EFFECTS/SYMPTOMS OF EXPOSURE****EYE CONTACT:** Irritation, burning of eyes, lachrymation may occur.**SKIN CONTACT:** After contact with this substance reddening and irritation of skin may occur.**INGESTION:** Irritation (if powder is ingested directly).**INHALATION:** After breathing of dust possible irritation of nose, respiratory tract, lungs:  
Cough, shortness of breath.**EYE CONTACT:** Irritation, burning of eyes, lachrymation may occur.**COMMENTS:** For detailed toxicological information see Section 11.**3. COMPOSITION / INFORMATION ON INGREDIENTS**

Chemical Name	Synonyms	Wt %	CAS #
Colesevelam Hydrochloride Powder for Oral Suspension and Welchol® Powder for Oral Suspension	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	75.00%	182815-44-7
Natural lemon Durarome®	Not available	7.07%	Not available
Natural and Artificial Orange Flavor	Not available	7.07%	Not available
Propylene glycol Alginate	Kelcoloid K3B426	3.77%	9005-37-2
Maltodextrin	Not available	2.64%	9050-36-6
Simethicone USP	Not available	1.13%	67762-90-7

**4. FIRST AID MEASURES****GENERAL INFORMATION:** Immediately remove any clothing soiled by the product.**EYES:** Immediately flush eyes with water for at least 15 minutes and call a physician. Remove contact lenses immediately.**SKIN:** Immediately wash with water and soap and rinse for at least 15 minutes.**INGESTION:** Seek immediate medical attention.**INHALATION:** Immediately supply fresh air and call a physician. Restore and or support breathing as required. In case of unconsciousness, place patient stably in side position for transportation.**ANTIDOTES:** No specific antidote.**MOST IMPORTANT SYMPTOMS AND EFFECTS:** Contact with dust may cause irritation of mucous membrane. Burning of eyes, mucous membranes and skin. Coughing, headache, indisposition, shortness of breath.**NOTES TO PHYSICIAN:** This product is a pharmaceutical ingredient. No product-specific symptoms are known.

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**COMMENTS:** Symptomatic treatment.

## 5. FIRE FIGHTING MEASURES

### FIRE FIGHTING PROCEDURES

**GENERAL PROCEDURES:** Evacuate personnel to a safe area. Keep personnel removed upwind of fire. Shut off source of fuel, if possible to do so without risk to firefighters or other personnel.

**FIRE FIGHTING EQUIPMENT:** Wear self-contained respiratory protective device. Chemical resistant protective suit. Under the protective suit a fire protective suit according to EN 469 should be applied. Do not generate dust. The dust can be explosive if concentration in air is sufficient.

**EXTINGUISHING MEDIA:** Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Do not spray a solid stream of water or foam directly into a pool of hot, burning liquid as this may cause frothing, and may intensify the fire.

**HAZARDOUS DECOMPOSITION PRODUCTS:** In case of fire, the following can be released: carbon monoxide (CO), CO<sub>2</sub>, hydrogen chloride (HCl) and nitrogen oxides (NO<sub>x</sub>).

Traces of formaldehyde may be generated due to oxidative thermal decomposition at temperatures greater than 150 degrees Celsius (°C) (300 degrees Fahrenheit [°F]). Exposure to formaldehyde can cause adverse effects such as skin and respiratory sensitization and eye and throat irritation. Formaldehyde is a potential carcinogen. Evaluate and control exposure to formaldehyde when warranted by conditions of use.

## 6. ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:** Only trained personnel with personal protective equipment should be allowed to enter area and clean up spills.

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:** Do not allow to enter sewers/ surface or ground water.

Do not allow product to reach sewage system or any water course.

Keep contaminated washing water and dispose of appropriately.

**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. Ensure adequate ventilation.

Chemical and oil resistant gloves, tightly sealed goggles, protective work clothing, NIOSH certified P95, P99, or P100 respirators should be used if exposures cannot be adequately controlled. A full face respirator can be used in place of the tight fitting goggles if protection against eye irritation is also required. 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).

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**Reference to other sections:** See Section 8 for information on personal protection equipment.  
 See Section 7 for information on safe handling  
 See Section 13 for disposal information.  
 Formation of explosive dust/air-mixtures is possible.

## 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 receptacle tightly sealed. Colesevelam hydrochloride is a hygroscopic material that will absorb water from the surrounding environment so keep containers tightly sealed. Store in cool, dry conditions. Recommended storage conditions are 25 °C and 60% relative humidity. Store away from oxidizing agents and strong bases.

**COMMENTS:** Avoid spillage of product into the environment.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE GUIDELINES

Chemical	ACGIH (TLV®)	NIOSH (REL)	OSHA (PEL)
Colesevelam Hydrochloride	N.E	N.E	N.E
Natural lemon Durarome®	N.E	N.E	N.E
Natural and Artificial Orange Flavor	N.E	N.E	N.E
Propylene glycol Alginate	N.E	N.E	N.E
Maltodextrin	N.E	N.E	N.E
Simethicone USP	N.E	N.E	N.E
N.E. = Not Established			

**ENGINEERING CONTROLS:** Adequate ventilation to control airborne levels of listed ingredients.

### PERSONAL PROTECTIVE EQUIPMENT

**EYES AND FACE:** Tightly sealed goggles.

**SKIN:** Chemical and oil resistant gloves.

**RESPIRATORY:** NIOSH certified P95, P99, or P100 respirators should be used if exposures cannot be adequately controlled. A full face respirator can be used in place of the tight fitting goggles if protection against eye irritation is also required.

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:** Use dust-proof protective suit.

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**WORK HYGIENIC PRACTICES:**

Keep away from food and beverages.

Immediately remove soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin

Avoid inhalation of powder.

Use good industrial hygiene practices in designing the workplace and developing work practices.

**NOTE:** If possible use this material only in closed systems and devices. In case of open plant systems (sampling devices, filling and discharging, cleansing works etc.) use local exhaust and collecting trays. Follow emission limit values. Measures in case of unwanted emissions should be established.

**9. PHYSICAL AND CHEMICAL PROPERTIES****APPEARANCE**

**PHYSICAL STATE:** Powder

**COLOR:** Whitish

**ODOR:** Amine-like

**ODOR THRESHOLD:** Not available.

**pH:** 3-4 (colesevelam hydrochloride).

**MELTING POINT:** Not available.

**FREEZING POINT:** Not available.

**INITIAL BOILING POINT:** Not available.

**BOILING RANGE:** Not available.

**FLASH POINT:** Not applicable.

**EVAPORATION RATE:** Not available.

**FLAMMABILITY:** Not available.

**AUTOIGNITION TEMPERATURE:** Not applicable.

**UPPER EXPLOSIVE LIMIT:** Not applicable.

**LOWER EXPLOSIVE LIMIT:** Not applicable.

**DUST EXPLOSION CLASS:** 100-1,000 g/m<sup>3</sup> (Method: Modified Hartmann-tube)

**SENSITIVITY TO STATIC DISCHARGE:** This powder is classified as "explosible" when suspended in air (see Handling and Storage in Section 7).

**SENSITIVITY TO IMPACT:** None known.

**VAPOR PRESSURE:** Not applicable.

**BULK DENSITY at 20 °C (68 °F):** 550 kg/m<sup>3</sup>

**VAPOR DENSITY:** Not applicable.

**RELATIVE DENSITY:** Not available.

**SOLUBILITY:** Insoluble (colesevelam hydrochloride)

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**PARTITION COEFFICIENT:** n-octanol/water; Not available.

**AUTO-IGNITION TEMPERATURE:** Not available.

**DECOMPOSITION TEMPERATURE:** Not available.

**VISCOSITY:** Not applicable.

**NOTE:** Material is not flammable. Excessive dust generation in air may create flammable or explosive environments.

## 10. STABILITY AND REACTIVITY

**CHEMICAL STABILITY:** Stable under normal conditions. The material is not sensitive to freeze-thaw cycling and is not photosensitive.

**REACTIVITY:** Not available.

**POSSIBILITY OF HAZARDOUS REACTIONS, POLYMERIZATION:** No hazardous polymerization known.

**CONDITIONS TO AVOID:** Heat, high temperatures.

**INCOMPATIBLE MATERIALS:** Strong oxidizing agents. Strong bases.

**HAZARDOUS DECOMPOSITION PRODUCTS:** In fire, CO and CO<sub>2</sub>, nitrogen oxides (NO<sub>x</sub>), hydrogen chloride (HCl).

Traces of formaldehyde may be generated due to oxidative thermal decomposition at temperatures greater than 150 degrees Celsius (°C) (300 degrees Fahrenheit [°F]). Exposure to formaldehyde can cause adverse effects such as skin and respiratory sensitization and eye and throat irritation. Formaldehyde is a potential carcinogen. Evaluate and control exposure to formaldehyde when warranted by conditions of use.

## 11. TOXICOLOGICAL INFORMATION

The powder is an irritant to the eyes, skin, and respiratory tract and can cause irritation of the gastrointestinal tract if ingested in pure form. The activity of colesevelam hydrochloride is not dependent on its dissolution or absorption since colesevelam hydrochloride is not absorbed *in vivo*. Colesevelam hydrochloride binds bile acids in the intestine, impeding their reabsorption.

### ACUTE EFFECTS

**EYES:** Irritant to eyes and mucous membranes.

**INHALATION** TC<sub>Lo</sub>: (Simethicone USP) Rat- 30 mg/kg/6H/4W intermittent (Respiration, Hemorrhage, Death).

**DERMAL** LD<sub>50</sub>: Not found.

**ORAL** LD<sub>50</sub>: (Colesevelam hydrochloride) Rat- 3,000 mg/kg.

TD<sub>Lo</sub>: (Colesevelam hydrochloride) Rat- 3,000 mg/kg/15D continuous (Behavioral- Food Intake).

LD<sub>50</sub>: (Propylene glycol alginate) Rat- 7,200 mg/kg.

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**POTENTIAL HEALTH EFFECTS****EYE CONTACT:** Irritating effect.**SKIN CONTACT:** Irritant to skin and mucus membrane.**INGESTION:** No irritating effect known.**INHALATION:** No irritating effect known.**SUBCHRONIC HEALTH EFFECTS:**

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

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

**TARGET ORGANS:** Skin, eyes, mucous membranes, respiratory tract, and gastrointestinal tract.**SENSITIZATION:** None found.**CHRONIC HEALTH EFFECTS:** No chronic effects known.**MEDICAL CONDITIONS AGGRAVATED:** None.**CARCINOGENICITY:**

Oral: (Colesevelam hydrochloride) 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: (Colesevelam hydrochloride) Rats- no observed effects up to 3 g/kg/day.

**MUTAGENICITY:**

Oral: (Colesevelam hydrochloride) Rats- no observed effects up to 3 g/kg/day.

**STOT—single exposure:** May cause respiratory irritation.**12. ECOLOGICAL INFORMATION****AQUATIC TOXICITY****Toxicity for fish:** LC<sub>50</sub> (96h) >100mg/l (*Brachydanio rerio*).**Toxicity for algae:** EC<sub>50</sub> (72h) >201 mg/l (*Selenastrum capricornutum*).**Toxicity for daphnia:** EC<sub>50</sub> (48h) >100 mg/l (*Daphnia magna*).**PERSISTENCE AND DEGRADABILITY**

Not easily biodegradable.

**BIOACCUMULATIVE POTENTIAL**

Not available.



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**MOBILITY IN SOIL**

Not available.

**OTHER ADVERSE EFFECTS**

Not available.

**COMMENTS:**

Ecotoxicological information for active ingredient, colesevelam hydrochloride.  
Generally not hazardous for water.

**13. DISPOSAL CONSIDERATIONS****WASTE TREATMENT METHODS**

**Recommendation:** Must not be disposed of together with household garbage.  
Do not allow product to reach sewage system.  
Must be specially treated adhering to official regulations.  
Recovery or recycling if possible.

**UNCLEANED PACKAGINGS**

**Recommendation:** Empty contaminated packagings thoroughly. They can be recycled after thorough and proper cleaning.  
Packagings that cannot be cleansed are to be disposed of in the same manner as the product.

**14. TRANSPORT INFORMATION**

UN Number	Not classified as dangerous for transport.
UN Proper Shipping Name	Not available.
Transport Hazard Class(es)	Not available.
Packing Group	Not available.
Environmental Hazards	Not applicable.
Transport in Bulk	Not applicable.
Special Precautions	Not applicable.

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## 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**SARA:**

**Section 355:** Substance is not listed.

**Section 313:** Substance is not listed.

**EPA TSCA Section 8 (b)- Inventory of chemical substances:** the following ingredients in Section 3 are listed on the TSCA inventory: Propylene Glycol, Alginate (Kelcoloid K3B426), Maltodextrin, and Simethicone USP.

**EPA Clean Air Act Title 42 Chapter 85- Hazardous Air Pollutants:** None

**California Proposition 65- Ingredients known to the state of California to cause cancer:** Acetaldehyde (trace constituent in orange flavoring, less than 0.00035% of total mixture).

**California Proposition 65- Ingredients known to the state of California to cause birth defects or other reproductive hazards:** None

**Proposition 65:**

**Chemicals known to cause cancer:** Substance is not listed.

**Chemicals known to cause reproductive toxicity for females:** Substance is not listed.

**Chemicals known to cause reproductive toxicity for males:** Substance is not listed.

**Chemicals known to cause developmental toxicity:** Substance is not listed.

**Carcinogenicity categories EPA (Environmental Protection Agency):** Substance is not listed.

**TLV (Threshold Limit Value established by ACGIH):** Substance is not listed.

**NIOSH-Ca (National Institute for Occupational Safety and Health):** Substance is not listed.

## 16. OTHER INFORMATION

**Abbreviations and acronyms:**

ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute Toxic Estimate

BZ: Brennzahl

CAS: Chemical Abstracts Service (Division of the American Chemical Society)

CLP: Regulation (EC) 1272/2008 on Classification, Labelling and Packaging of Substances

EbC50: Effect concentration: Biomass

EINECS: European Inventory of Existing Commercial Chemical Substances

EPA: Environmental Protection Agency

ErC50: Effect concentration: Growth

HMIS: Hazardous Materials Identification System (USA)

IATA: International Air Transport Association

IBC: Intermediate Bulk Container

IC50: Medium inhibitoric concentration

IMDG: International Maritime Dangerous Goods Code

ipr: intraperitoneal

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

LDLo: Minimum lethal dose

MARPOL: Marine Pollution Convention (International Convention for the Prevention of Pollution from Ships)

NFPA: National Fire Protection Association (USA)

NIOSH: National Institute for Occupational Safety and Health

PBT: Persistent, Bioaccumulative and Toxic Substances

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer  
(Regulations Concerning the International Transport of Dangerous Goods by Rail)

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SARA: Superfund Amendments and Reauthorization Act

scu: subcutane

STOT-SE: Single Target Organ Toxicity - Single Exposure

STOT-RE: Single Target Organ Toxicity - Repeated Exposure

TLV: Threshold Limit Value established by ACGIH)

vPvB: Very Persistent and Very Bioaccumulative Substances

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Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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