

SAFETY DATA SHEETS

This SDS packet was issued with item:

078939432

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078936420

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • Cholestyramine for Oral Suspension USP, 4g/9g Powder

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Used to lower high levels of cholesterol in the blood, especially low-density lipoprotein (LDL).

Details of the supplier of the safety data sheet

Manufacturer • ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, MN 56623
United States
www.anipharmaeaceuticals.com
customerservice@anipharmaeaceuticals.com

Telephone (General) • 800.434.1121 ext. 3607

Emergency telephone number

Manufacturer • 800-308-6755

Section 2: Hazard Identification

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012 • Eye Irritation 2
Reproductive Toxicity 2
Combustible Dust

Label elements

OSHA HCS 2012

WARNING



Hazard statements • Causes serious eye irritation
Suspected of damaging fertility or the unborn child.
May form combustible dust concentrations in air.

Precautionary statements

Prevention • Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF exposed or concerned: Get medical advice/attention.

Storage/Disposal • Store locked up.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

OSHA HCS 2012

- Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance.

Mixtures

Composition					
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Sucrose	CAS:57-50-1	N/A	Ingestion/Oral-Rat LD50 • 29700 mg/kg	OSHA HCS 2012: Comb. Dust	NDA
Propylene glycol alginate	CAS:9005-37-2	N/A	NDA	OSHA HCS 2012: Comb. Dust	NDA
Flavor – Orange, WONF #S-261	NDA	N/A	NDA	OSHA HCS 2012: Not Classified	NDA
Citric acid	CAS:77-92-9	N/A	Ingestion/Oral-Rat LD50 • 3 g/kg	OSHA HCS 2012: Comb. Dust; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3: Resp. Irrit.	NDA
Cholestyramine	CAS:11041-12-6	N/A	NDA	OSHA HCS 2012: Repr. 2; Comb. Dust	NDA
C.I. Acid Yellow 3	CAS:8004-92-0	N/A	NDA	OSHA HCS 2012: Acute Tox. 4 (Orl)	NDA
Arabic gum	CAS:9000-01-5	N/A	NDA	OSHA HCS 2012: Eye Irrit. 2; STOT SE 3: Resp. Irrit.	NDA

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Give artificial respiration if victim is not breathing. If signs/symptoms continue, get medical attention.

Skin

- In case of contact with substance, immediately flush skin with running water for at least 20 minutes. If irritation develops and persists, get medical attention.

Eye

- In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion

- Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms and effects, both acute and delayed

- Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- LARGE FIRE: Water spray, fog or regular foam.
 - SMALL FIRES: Dry chemical, CO2, water spray or regular foam.

Unsuitable Extinguishing Media

- No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Hazardous Combustion Products

- No data available

Advice for firefighters

- Wear positive pressure self-contained breathing apparatus (SCBA). Structural firefighters' protective clothing will only provide limited protection.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

- Ventilate enclosed areas. Do not walk through spilled material. Use appropriate Personal Protective Equipment (PPE)

Emergency Procedures

- ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep unauthorized personnel away.

Environmental precautions

- Avoid run off to waterways and sewers.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Avoid generating dust.
Use clean nonsparking tools to collect material.
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use only with adequate ventilation. Keep away from heat, sparks, and flame. Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Wear appropriate personal protective equipment, avoid direct contact. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Conditions for safe storage, including any incompatibilities

Storage

- Keep container closed. Store at 20° to 25°C (68° to 77°F)

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines				
	Result	ACGIH	NIOSH	OSHA
Sucrose (57-50-1)	TWAs	10 mg/m ³ TWA	10 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable dust)	15 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable fraction)

Exposure controls

Engineering Measures/Controls

- Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is not leakage from the equipment). It is recommended that dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Use only appropriately classified electrical equipment.

Personal Protective Equipment

Respiratory

- For limited exposure use an N95 dust mask. For prolonged exposure use an air-purifying respirator with high efficiency particulate air (HEPA) filters. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face

- Wear safety goggles.

Skin/Body

- Wear appropriate gloves. Wear long sleeves and/or protective coveralls.

Environmental Exposure Controls

- Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways. Follow best practice for site management and disposal of waste.

Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygiene

NIOSH = National Institute of Occupational Safety and Health

OSHA = Occupational Safety and Health Administration

TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Yellow, free-flowing powder.
Color	Yellow	Odor	No data available
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	2.5 to 4.5
Specific Gravity/Relative Density	No data available	Water Solubility	Appreciable 10 to 99 %
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			

Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- Hazardous polymerization not indicated.

Conditions to avoid

- Avoid generating dust. Keep away from heat, sparks and flame.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Cholestyramine (N/A)	11041-12-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • >4 g/kg; Reproductive: Ingestion/Oral-Rat TDLo • 5500 mg/kg (7-17D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:</i> Musculoskeletal system
Arabic gum (N/A)	9000-01-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >16 g/kg; Irritation: Eye-Rabbit • 36 mg 5 Hour(s) • Severe irritation; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 1260 g/kg 13 Week(s)-Continuous; <i>Liver:Changes in liver weight; Kidney, Ureter, and Bladder:Changes in bladder weight; Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol);</i> Mutagen: Dominant lethal test • Ingestion/Oral-Rat • 54600 mg/kg 10 Week(s)-Continuous; Reproductive: Ingestion/Oral-Rat TDLo • 350 g/kg (10W male); <i>Reproductive Effects:Effects on Fertility:Pre-implantation mortality</i>
Citric acid (N/A)	77-92-9	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3 g/kg; Inhalation-Rat TCLo • 180 mg/m ³ ; <i>Lungs, Thorax, or Respiration:Other changes; Liver:Liver function tests impaired; Biochemical:Enzyme inhibition, induction, or change in blood or tissue levels:Dehydrogenases;</i> Irritation: Eye-Rabbit • 750 µg 24 Hour(s) • Severe irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation
Propylene glycol alginate (N/A)	9005-37-2	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7200 mg/kg
C.I. Acid Yellow 3 (N/A)	8004-92-0	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Sucrose (N/A)	57-50-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 29700 mg/kg; <i>Behavioral:Somnolence (general depressed activity); Lungs, Thorax, or Respiration:Cyanosis; Gastrointestinal:Hypermotility, diarrhea;</i> Mutagen: Cytogenetic analysis • Unreported Route-Hamster • Lung (Somatic cell) • 10 g/L; Cytogenetic analysis • Unreported Route-Hamster • Ovary (Somatic cell) • 275 mmol/L;

Reproductive: Ingestion/Oral-Rat TDLo • 1548 g/kg (21D pre/1-22D preg); *Reproductive Effects: Specific Developmental Abnormalities:* **Central nervous system**

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012 • No data available
Skin corrosion/Irritation	OSHA HCS 2012 • No data available
Serious eye damage/Irritation	OSHA HCS 2012 • Eye Irritation 2
Skin sensitization	OSHA HCS 2012 • No data available
Respiratory sensitization	OSHA HCS 2012 • No data available
Aspiration Hazard	OSHA HCS 2012 • No data available
Carcinogenicity	OSHA HCS 2012 • No data available
Germ Cell Mutagenicity	OSHA HCS 2012 • No data available
Toxicity for Reproduction	OSHA HCS 2012 • Toxic to Reproduction 2
STOT-SE	OSHA HCS 2012 • No data available
STOT-RE	OSHA HCS 2012 • No data available

Potential Health Effects

Inhalation

- Acute (Immediate)**
- Exposure to dust may cause irritation. Processes such as cutting, grinding, crushing, or impact may result in generation of excessive amounts of airborne dusts in the workplace. Nuisance dust may affect the lungs but reactions are typically reversible.
- Chronic (Delayed)**
- No data available

Skin

- Acute (Immediate)**
- Exposure to dust may cause mechanical irritation.
- Chronic (Delayed)**
- No data available.

Eye

- Acute (Immediate)**
- Causes serious eye irritation. Excessive concentrations of nuisance dust in the workplace may reduce visibility and may cause unpleasant deposits in eyes.
- Chronic (Delayed)**
- No data available.

Ingestion

- Acute (Immediate)**
- Excessive concentrations of nuisance dust in the workplace may cause mechanical irritation to mucous membranes.
- Chronic (Delayed)**
- No data available

Reproductive Effects

- Repeated and prolonged exposure may cause reproductive effects.

Key to abbreviations

LD = Lethal Dose

TD = Toxic Dose

Section 12 - Ecological Information

Toxicity

- The product is not classified as environmentally hazardous.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

- No studies have been found.

Section 13 - Disposal Considerations**Waste treatment methods****Product waste**

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA

Special precautions for user

- None specified.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Inventory		
Component	CAS	TSCA
Arabic gum	9000-01-5	Yes
Cholestyramine	11041-12-6	Yes
Citric acid	77-92-9	Yes
Propylene glycol alginate	9005-37-2	Yes
Sucrose	57-50-1	Yes

United States**Labor****U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals**

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

Environment**U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants**

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed

• Propylene glycol alginate	9005-37-2	Not Listed
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United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Arabic gum	9000-01-5	Not Listed
• Sucrose	57-50-1	Not Listed
• Citric acid	77-92-9	Not Listed
• Cholestyramine	11041-12-6	Not Listed
• Propylene glycol alginate	9005-37-2	Not Listed

Section 16 - Other Information

Revision Date • 21/June/2018

Preparation Date • 21/June/2018

Disclaimer/Statement of Liability • The information herein is given in good faith but no warranty, expressed or implied, is made.

Key to abbreviations

NDA = No Data Available