

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Substance

Product Name: FIRST[®] - Omeprazole

CAS No: Not applicable

Product Code: Not applicable

Synonyms: Not applicable

1.2. Intended Use of the Product

Use of the Substance/Mixture: Gastrointestinal drug

1.3. Name, Address, and Telephone of the Responsible Party

Company

CutisPharma, Inc.

841 Woburn Street

Wilmington, MA 01887

781-935-8141

www.CutisPharma.com

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 (Chemtrec 24 hour emergency telephone number)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Skin Irrit. 2 H315

Eye Irrit. 2 H319

Skin Sens. 1 H317

STOT SE 3 H335

Comb. Dust

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS07

Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

Precautionary Statements (GHS-US) :

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water.

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Name : Omeprazole

CAS No : Not applicable

Name	Product Identifier	%	GHS-US classification
Omeprazole	(CAS No) 73590-58-6	.002	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 STOT SE 3, H335 Comb. Dust
Water	(CAS No) 7732-18-5	80 - 82	Not classified
Sodium bicarbonate	(CAS No) 144-55-8	8.4	Not classified
1,2-Propanediol	(CAS No) 57-55-6	5	Not classified
Oxirane, methyl-, polymer with oxirane	(CAS No) 9003-11-6	2	Aquatic Chronic 3, H412
Trisodium citrate dihydrate	(CAS No) 6132-04-3	1	Comb. Dust
ART STRAWBERRY FLAVOR F-2093	(CAS No) Not available	0.75	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Benzyl alcohol	(CAS No) 100-51-6	0.5	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
1,6-Dichloro-1,6-dideoxy-.beta.-D-fructofuranosyl 4-chloro-4-deoxy-.alpha.-D-galactose	(CAS No) 56038-13-2	0.45	Comb. Dust
Xanthan gum	(CAS No) 11138-66-2	0.4	Comb. Dust
.alpha.-D-Glucopyranosiduronic acid, (3.beta.,20.beta.)-20-carboxy-11-oxo-30-norolean-12-en-3-yl 2-O-.beta.-D-glucopyranuronosyl-, monoammonium salt	(CAS No) 53956-04-0	0.07	Comb. Dust
FD and C Red No. 40	(CAS No) 25956-17-6	0.003	Comb. Dust
Silica gel	(CAS No) 63231-67-4	0.002 - 0.01	Not classified
Polyethylene glycol stearate	(CAS No) 9004-99-3	0.002 - 0.01	Comb. Dust

Full text of H-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes skin irritation. May cause respiratory irritation. Skin sensitization.

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes. Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis. May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

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Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Sulfur oxides. Toxic fumes may be released.

Other Information: Risk of dust explosion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, hot surfaces. – No smoking.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store the kit and reconstituted suspension at refrigerated temperatures (5 ± 3°C). Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong acids, strong bases, strong oxidizers.

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7.3. Specific End Use(s)

Gastrointestinal drug

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all 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.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: A slightly hazy, red liquid
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

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9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Omeprazole (73590-58-6)	
LD50 Oral Rat	2210 mg/kg
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h
FD and C Red No. 40 (25956-17-6)	
LD50 Oral Rat	> 10000 mg/kg
LD50 Dermal Rabbit	> 10000 mg/kg
.alpha.-D-Glucopyranosiduronic acid, (3.beta.,20.beta.)-20-carboxy-11-oxo-30-norolean-12-en-3-yl 2-O-.beta.-D-glucopyranuronosyl-, monoammonium salt (53956-04-0)	
LD50 Oral Rat	> 10 g/kg
Oxirane, methyl-, polymer with oxirane (9003-11-6)	
LD50 Oral Rat	16 g/kg
LC50 Inhalation Rat	320 mg/m ³ (Exposure time: 4 h)
1,2-Propanediol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg
Polyethylene glycol stearate (9004-99-3)	
LD50 Oral Rat	53 ml/kg
Sodium bicarbonate (144-55-8)	
LD50 Oral Rat	4220 mg/kg

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes. Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis. May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (Algae)	770 mg/l

1,2-Propanediol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Sodium bicarbonate (144-55-8)	
LC50 Fish 1	8250 - 9000 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	2350 mg/l (Exposure time: 48 h - Species: Daphnia magna)

12.2. Persistence and Degradability

Omeprazole	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

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Bioaccumulative Potential	Not established.
Benzyl alcohol (100-51-6)	
Log Pow	1.1
1,2-Propanediol (57-55-6)	
BCF Fish 1	< 1
Log Pow	-0.92

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
FD and C Red No. 40 (25956-17-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
.alpha.-D-Glucopyranosiduronic acid, (3.beta.,20.beta.)-20-carboxy-11-oxo-30-norolean-12-en-3-yl 2-O-.beta.-D-glucopyranuronosyl-, monoammonium salt (53956-04-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Oxirane, methyl-, polymer with oxirane (9003-11-6)	

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Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).
1,2-Propanediol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Silica gel (63231-67-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Polyethylene glycol stearate (9004-99-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).
Sodium bicarbonate (144-55-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Xanthan gum (11138-66-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists.

Benzyl alcohol (100-51-6)
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List
1,2-Propanediol (57-55-6)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List
Silica gel (63231-67-4)
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date	: 10/17/2017
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Comb. Dust	Combustible Dust
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.