SECTION 1: IDENTIFICATION

1.1. Product Identifier
Product Form: Substance
Product Name: FIRST® - Lansoprazole
CAS-No.: Not applicable
Product Code: Not applicable
Synonyms: Not applicable

1.2. Intended Use of the Product
Use of the Substance/Mixture: Anti-ulcerative 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. 2A H319
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): 

Signal Word (GHS-US): Warning

Hazard Statements (GHS-US): May form combustible dust concentrations in air.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.

Precautionary Statements (GHS-US): P261 - Avoid breathing vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
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.
P321 - Specific treatment (see section 4 on this SDS).
P332+P313 - If skin irritation 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
3.1. Substance

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole</td>
<td>(CAS-No.) 103577-45-3</td>
<td>0.003</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td>(CAS No) 7732-18-5</td>
<td>80 - 82</td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td>Water</td>
<td>(CAS No) 144-55-8</td>
<td>8.4</td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>(CAS No) 57-55-6</td>
<td>5</td>
<td>Comb. Dust</td>
</tr>
<tr>
<td>Trisodium citrate dihydrate</td>
<td>(CAS No) 9003-11-6</td>
<td>2</td>
<td>Comb. Dust</td>
</tr>
<tr>
<td>Oxirane, methyl-, polymer with oxirane</td>
<td>(CAS No) 6132-04-3</td>
<td>1</td>
<td>Skin Irrit. 2, H315</td>
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<tr>
<td>ART STRAWBERRY FLAVOR F-2093</td>
<td>(CAS No) Not available</td>
<td>0.75</td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>(CAS No) 100-51-6</td>
<td>0.5</td>
<td>Flm. Liq. 4, H227</td>
</tr>
<tr>
<td>1,6-Dichloro-1,6-dideoxy-.beta.-D-fructofuranosyl 4-chloro-4-deoxy-.alpha.-D-galactose</td>
<td>(CAS No) 56038-13-2</td>
<td>0.45</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
<tr>
<td>Xanthan gum</td>
<td>(CAS No) 11138-66-2</td>
<td>0.4</td>
<td>Acute Tox. 4 (Inhalation:dust,mist), H332</td>
</tr>
<tr>
<td>.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</td>
<td>(CAS No) 53956-04-0</td>
<td>0.07</td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td>FD and C Red No. 40</td>
<td>(CAS No) 25956-17-6</td>
<td>0.003</td>
<td>Aquatic Acute 2, H401</td>
</tr>
<tr>
<td>Silica gel</td>
<td>(CAS No) 63231-67-4</td>
<td>0.002 - 0.01</td>
<td>Not classified</td>
</tr>
<tr>
<td>Polyethylene glycol stearate</td>
<td>(CAS No) 9004-99-3</td>
<td>0.002 - 0.01</td>
<td>Comb. Dust</td>
</tr>
</tbody>
</table>

3.2. Mixture

Not applicable

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 serious eye irritation. Causes skin irritation. May cause respiratory irritation.

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.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

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.
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. Avoid all contact with skin, eyes, or 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).

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. 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. Contact competent authorities after a spill.

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 skin, eyes 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)
Anti-ulcerative 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.


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
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: Dust accumulation (to minimize explosion hazard). Sparks, heat, open flame and other sources of ignition. Direct sunlight, extremely high or low temperatures, and incompatible materials.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Route</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole (103577-45-3)</td>
<td>Oral Rat</td>
<td>LD50 &gt; 5 g/kg</td>
</tr>
<tr>
<td>Benzyl alcohol (100-51-6)</td>
<td>Oral Rat</td>
<td>LD50 1230 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Dermal Rabbit</td>
<td>LD50 &gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Inhalation Rat</td>
<td>LC50 &gt; 4.178 mg/l/4h</td>
</tr>
<tr>
<td></td>
<td>ATE (Dust/Mist)</td>
<td>1.50 mg/l/4h</td>
</tr>
<tr>
<td>FD and C Red No. 40 (25956-17-6)</td>
<td>Oral Rat</td>
<td>LD50 &gt; 10000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Dermal Rabbit</td>
<td>LD50 &gt; 10000 mg/kg</td>
</tr>
<tr>
<td>.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)</td>
<td>Oral Rat</td>
<td>LD50 &gt; 10 g/kg</td>
</tr>
<tr>
<td>Oxirane, methyl-, polymer with oxirane (9003-11-6)</td>
<td>Oral Rat</td>
<td>LD50 16 g/kg</td>
</tr>
<tr>
<td></td>
<td>Inhalation Rat</td>
<td>LC50 320 mg/m³ (Exposure time: 4 h)</td>
</tr>
<tr>
<td>1,2-Propanediol (57-55-6)</td>
<td>Oral Rat</td>
<td>LD50 20 g/kg</td>
</tr>
<tr>
<td></td>
<td>Dermal Rabbit</td>
<td>LD50 20800 mg/kg</td>
</tr>
<tr>
<td>Polyethylene glycol stearate (9004-99-3)</td>
<td>Oral Rat</td>
<td>LD50 53 ml/kg</td>
</tr>
<tr>
<td>Sodium bicarbonate (144-55-8)</td>
<td>Oral Rat</td>
<td>LD50 4220 mg/kg</td>
</tr>
</tbody>
</table>

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: Not classified

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.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

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

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.
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<table>
<thead>
<tr>
<th>Benzyl alcohol (100-51-6)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish 1</td>
<td>460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>23 mg/l (Exposure time: 48 h - Species: water flea)</td>
</tr>
<tr>
<td>LC50 Fish 2</td>
<td>10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])</td>
</tr>
<tr>
<td>ErC50 (Algae)</td>
<td>770 mg/l</td>
</tr>
</tbody>
</table>

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

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

### 12.2. Persistence and Degradability

**FIRST® - Lansoprazole**

Persistence and Degradability: Not established.

### 12.3. Bioaccumulative Potential

**Omeprazole**

Bioaccumulative Potential: Not established.

**Benzyl alcohol (100-51-6)**

Log Pow: 1.1

**1,2-Propanediol (57-55-6)**

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


Listed on the United States TSCA (Toxic Substances Control Act) inventory

**Oxirane, methyl-, polymer with oxirane (9003-11-6)**

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)).

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EN [English US]
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### 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

<table>
<thead>
<tr>
<th>EPA TSCA Regulatory Flag</th>
<th>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)).</th>
</tr>
</thead>
</table>

### 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

<table>
<thead>
<tr>
<th>EPA TSCA Regulatory Flag</th>
<th>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)).</th>
</tr>
</thead>
</table>

### 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

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>05/22/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Information</td>
<td>This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200</td>
</tr>
</tbody>
</table>

**GHS Full Text Phrases:**

<table>
<thead>
<tr>
<th>Comb. Dust</th>
<th>Combustible Dust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
</tbody>
</table>

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.

SDS US (GHS HazCom)