

**SECTION 1: IDENTIFICATION**

**1.1. Product Identifier**

**Product Form:** Substance

**Product Name:** FIRST® - Lansoprazole

**CAS-No.:** 103577-45-3

**Product Code:** 080-10, 080-05, 080-03

**Synonyms:** NDC # 65628-080-10, NDC # 65628-080-05, NDC # 65628-080-03

**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](http://www.CutisPharma.com)

**Manufacturer**

Marlex Pharmaceuticals  
50 McCullough Drive  
New Castle, DE 19720  
302-328-3355

**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)** :



GHS07

**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.  
H335 - May cause respiratory irritation.

**Precautionary Statements (GHS-US)** :

P261 - Avoid breathing vapors, mist, or spray.  
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.  
P271 - Use only outdoors or in a well-ventilated area.  
P280 - Wear protective gloves, protective clothing, and eye protection.  
P302+P352 - If on skin: Wash with plenty of water.  
P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.  
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P312 - Call a poison center or doctor if you feel unwell.  
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.  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
P405 - Store locked up.  
P501 - Dispose of contents/container in accordance with local, regional, national,

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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

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Name : FIRST® - Lansoprazole

CAS-No. : 103577-45-3

| Name         | Product Identifier    | %   | GHS-US classification   |
|--------------|-----------------------|-----|---|
| Lansoprazole | (CAS-No.) 103577-45-3 | 100 | Skin Irrit. 2, H315<br>Eye Irrit. 2A, H319<br>STOT SE 3, H335<br>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 Inhalation:** Using proper respiratory protection, move the exposed person to fresh air at once.

Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

**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.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Sulfur oxides. Nitrogen oxides. Hydrogen Fluoride (HF). Hydrogen sulfide. Phosgene.

**Other Information:** Risk of dust explosion.

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## 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).

**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. 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 in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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

### 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.

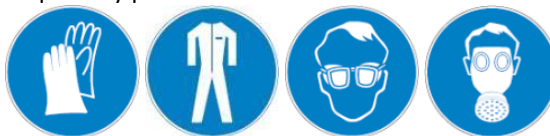
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## Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



## 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                         | : Solid                   |
| Appearance                             | : White to brownish-white |
| 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

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|               |          |
|---------------|----------|
| LD50 Oral Rat | > 5 g/kg |
|---------------|----------|

**Skin Corrosion/Irritation:** Causes skin irritation.

**Serious Eye Damage/Irritation:** Causes serious eye irritation.

**Respiratory or Skin Sensitization:** Not classified

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**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.

### 12.2. Persistence and Degradability

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|                               |                  |
|-------------------------------|------------------|
| Persistence and Degradability | Not established. |
|-------------------------------|------------------|

### 12.3. Bioaccumulative Potential

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|                           |                  |
|---------------------------|------------------|
| Bioaccumulative Potential | Not established. |
|---------------------------|------------------|

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

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|                                     |   |
|-------------------------------------|---|
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard<br>Fire hazard<br>Sudden release of pressure hazard |
|-------------------------------------|---|

15.2. **US State Regulations** Neither this product nor its chemical components appear on any US state lists.

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

Revision Date : 05/22/2017

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. 2A | Serious eye damage/eye irritation Category 2A |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2          |

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|           |   |
|-----------|---|
| STOT SE 3 | Specific target organ toxicity (single exposure) Category 3 |
| H315      | Causes skin irritation                                      |
| 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.*

SDS US (GHS HazCom)