

**SECTION 1: IDENTIFICATION**

**1.1. Product Identifier**

**Product Form:** Substance  
**Product Name:** FIRST® – Mouthwash BLM  
**CAS No:** Not applicable  
**Product Code:** 65628-050-04, 65628-050-01  
**Synonyms:** Not applicable

**1.2. Intended Use of the Product**

**Use of the Substance/Mixture:** Local anesthetic, Anti-arrhythmi 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)

**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**

Acute Tox. 3 (Oral) H301  
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)** : H302 - Harmful if swallowed.  
**Precautionary Statements (GHS-US)** : P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P301+P310 - If swallowed: Immediately call a poison center or doctor.  
P321 - Specific treatment (see section 4 on this SDS).  
P330 - Rinse mouth.  
P405 - Store locked up.  
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

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1. Substance**

**Name** : FIRST – Mouthwash BLM  
**CAS No** : Not applicable

Name	Product Identifier	%	GHS-US classification
Lidocaine Hydrochloride	(CAS No) 6108-05-0	.007	Acute Tox. 3 (Oral), H301 Comb. Dust
Diphenhydramine hydrochloride	(CAS-No.) 147-24-0	.001	Acute Tox. 4 (Oral), H302 Comb. Dust

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Water	(CAS-No.) 7732-18-5	65.0652	Not classified
D-Glucitol	(CAS-No.) 50-70-4	20	Comb. Dust
Magnesium hydroxide	(CAS-No.) 1309-42-8	8.342	Not classified
Aluminum hydroxide (Al(OH) <sub>3</sub> )	(CAS-No.) 21645-51-2	5.105	Not classified
Cellulose, 2-hydroxyethyl ether	(CAS-No.) 9004-62-0	0.5	Comb. Dust
Benzyl alcohol	(CAS-No.) 100-51-6	0.3379	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Benzaldehyde	(CAS-No.) 100-52-7	0.032 - 0.04	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Aquatic Acute 3, H402
Benzoic acid, 4-hydroxy-, butyl ester	(CAS-No.) 94-26-8	0.0327	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 Comb. Dust
Silica gel	(CAS-No.) 63231-67-4	0.004449 - 0.022245	Not classified
Polyethylene glycol stearate	(CAS-No.) 9004-99-3	0.004449 - 0.022245	Comb. Dust
Propyl 4-hydroxybenzoate	(CAS-No.) 94-13-3	0.0218	Comb. Dust Aquatic Acute 2, H401
Sodium saccharin	(CAS-No.) 128-44-9	0.02	Not classified

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:** If feeling unwell, do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Toxic if swallowed.

**Symptoms/Injuries After Inhalation:** Dust may be harmful or cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

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

**Symptoms/Injuries After Ingestion:** This material is toxic in small amounts orally, and can cause adverse health effects or death.

**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.

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**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>). Nitrogen oxides. Hydrogen chloride gas.

**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).

**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. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing. Do not breathe dust. 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. Store locked up.

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

### 7.3. Specific End Use(s)

Local anesthetic, Anti-arrhythmi drug

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm
Benzaldehyde (100-52-7)		
USA AIHA	WEEL TWA (ppm)	2 ppm
USA AIHA	WEEL STEL (ppm)	4 ppm
USA AIHA	AIHA chemical category	Skin sensitizer

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## 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. 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	: Liquid
Appearance	: Slightly hazy, Pink 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.

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**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:** Oral: Toxic if swallowed.

<b>Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate (6108-05-0)</b>	
LD50 Oral Rat	292 mg/kg (Mouse)
<b>Diphenhydramine hydrochloride (147-24-0)</b>	
LD50 Oral Rat	700 mg/kg
<b>Aluminum hydroxide (Al(OH)3) (21645-51-2)</b>	
LD50 Oral Rat	> 5000 mg/kg
<b>Polyethylene glycol stearate (9004-99-3)</b>	
LD50 Oral Rat	53 ml/kg
<b>D-Glucitol (50-70-4)</b>	
LD50 Oral Rat	15.9 g/kg
<b>Sodium saccharin (128-44-9)</b>	
LD50 Oral Rat	10000 mg/kg
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	
LD50 Oral Rat	> 5000 mg/kg
<b>Benzyl alcohol (100-51-6)</b>	
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
<b>Benzaldehyde (100-52-7)</b>	
LD50 Oral Rat	1292 mg/kg
LD50 Dermal Rabbit	> 1250 mg/kg
<b>Magnesium hydroxide (1309-42-8)</b>	
LD50 Oral Rat	8500 mg/kg

**Skin Corrosion/Irritation:** Not classified

**Serious Eye Damage/Irritation:** Not classified

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Dust may be harmful or cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

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

**Symptoms/Injuries After Ingestion:** This material is toxic in small amounts orally, and can cause adverse health effects or death.

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. Not classified.

<b>Sodium saccharin (128-44-9)</b>	
LC50 Fish 1	16400 - 20400 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	

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LC50 Fish 1	4.1 (4.1 - 8.8) mg/l (Exposure time: 96 h - Species: Danio rerio)
EC50 Daphnia 1	7.97 (7.97 - 32.3) mg/l
NOEC Chronic Algae	2.1 mg/l
<b>Benzyl alcohol (100-51-6)</b>	
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
<b>Benzaldehyde (100-52-7)</b>	
LC50 Fish 1	10.6 - 11.8 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [flow-through])
LC50 Fish 2	12.69 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

## 12.2. Persistence and Degradability

<b>Cherry Flavor Suspension</b>	
Persistence and Degradability	Not established.

## 12.3. Bioaccumulative Potential

<b>Cherry Flavor Suspension</b>	
Bioaccumulative Potential	Not established.
<b>Sodium saccharin (128-44-9)</b>	
Log Pow	0.91
<b>Benzyl alcohol (100-51-6)</b>	
Log Pow	1.1
<b>Benzaldehyde (100-52-7)</b>	
BCF Fish 1	(no significant bioaccumulation)
Log Pow	1.48 (at 20 °C)

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

<b>Lidocaine Hydrochloride USP (6108-05-0)</b>	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Fire hazard Sudden release of pressure hazard
<b>Aluminum hydroxide (Al(OH)3) (21645-51-2)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Silica gel (63231-67-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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<b>Polyethylene glycol stearate (9004-99-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	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)).
<b>D-Glucitol (50-70-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Cellulose, 2-hydroxyethyl ether (9004-62-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	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)).
<b>Sodium saccharin (128-44-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	TP - TP - indicates a substance that is the subject of a proposed Section 4 test rule under TSCA.
<b>Benzoic acid, 4-hydroxy-, butyl ester (94-26-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Benzyl alcohol (100-51-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Benzaldehyde (100-52-7)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Magnesium hydroxide (1309-42-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

## 15.2. US State Regulations

<b>Silica gel (63231-67-4)</b>	
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List	
<b>Sodium saccharin (128-44-9)</b>	
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Special Hazardous Substances U.S. - Pennsylvania - RTK (Right to Know) List	
<b>Benzyl alcohol (100-51-6)</b>	
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List	
<b>Benzaldehyde (100-52-7)</b>	
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List	

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

<b>Revision Date</b>	: 10/18/2017
<b>Other Information</b>	: 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:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4

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Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life

*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)