# FIRST® - Atenolol 2 mg/mL (300mL)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: N/A Date of Issue: 09/20/2018 Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Substance

Product Name: FIRST® - Atenolol 2mg/ml (300ml)

**CAS-No.:** Not applicable

**Product Code:** NDC 65628-210-10

**Synonyms:** Not applicable

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Beta-blocker 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**

| | |
|---|---|
| Car. 2 | H351 |
| Rep. 2 | H361d |
| Lact. | H362 |

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

### 2.2. Label Elements

**GHS-US Labeling**

**Hazard Pictograms (GHS-US)** :

GHS08

**Signal Word (GHS-US)** : Warning

**Hazard Statements (GHS-US)** : H351 - Suspected of causing cancer
H361d - Suspected of damaging the unborn child
H362 - May cause harm to breast-fed children

**Precautionary Statements (GHS-US)** : P201 - Obtain special instructions before use
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P361 - Remove/Take off immediately all contaminated clothing
P501 - Dispose of contents/container to an approved incineration plant

### 2.3. Other Hazards

May produce an allergic reaction

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name : FIRST® - Atenolol 2mg/mL (300mL)

CAS-No. : N/A

| Name | Product Identifier | % | GHS-US classification |
|---|---|---|---|
| Atenolol | (CAS-No.) 29122-68-7 | .02% | Car. 2; H351<br>Rep. 2; H361d<br>Lact. H362 |
| Water | (CAS No) 7732-18-5 | 99 - 99.5% | Not classified |
| 1,6-Dichloro-1,6-dideoxy-.beta.-D-fructofuranosyl 4-chloro-4-deoxy-.alpha.-D-galactose | (CAS No) 56038-13-2 | 0.15 | Comb. Dust |
| Citric acid | (CAS No) 77-92-9 | 0.11 | Eye Irrit. 2A, H319<br>Comb. Dust |
| Sodium benzoate | (CAS No) 532-32-1 | 0.09 | Eye Irrit. 2A, H319<br>Comb. Dust |
| Acetic acid | (CAS No) 64-19-7 | 0.01 - 0.015 | Flam. Liq. 3, H226<br>Skin Corr. 1A, H314<br>Eye Dam. 1, H318<br>Aquatic Acute 3, H402 |
| Methyl anthranilate | (CAS No) 134-20-3 | 0.01 - 0.015 | Eye Irrit. 2A, H319 |
| Hexanoic acid | (CAS No) 142-62-1 | 0.0025 - 0.00375 | Acute Tox. 4 (Inhalation:dust,mist), H332<br>Skin Corr. 1C, H314<br>Eye Dam. 1, H318<br>Aquatic Acute 3, H402 |
| 6-Octen-1-ol, 3,7-dimethyl-, acetate | (CAS No) 150-84-5 | 0.00025 - 0.0005 | Skin Irrit. 2, H315<br>Aquatic Chronic 2, H411 |
| C.I. Acid Yellow 3 | (CAS No) 8004-92-0 | 0.0002 | Acute Tox. 4 (Oral), H302 |
| FD and C Red No. 40 | (CAS No) 25956-17-6 | 0.000038 | Comb. Dust |

Full text of H-phrases: see section 16

## 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 or if you feel unwell.

**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 large consumptions of product have been consumed or more than the amount recommended. Rinse mouth. Do NOT induce vomiting. Obtain medical attention if feeling unwell.

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

**Symptoms/Injuries:** Skin sensitization.

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

**Symptoms/Injuries After Skin Contact:** 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. May cause: nausea, diarrhea.

**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:** Not applicable.

**Explosion Hazard:** Not applicable.

**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, $CO_2$). Nitrogen oxides. Hydrogen chloride gas. Phosgene.

**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 prolonged contact with eyes, skin and clothing. Avoid breathing 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 at temperatures between 15 °C and 30 °C. Keep away from heat. Keep container tightly closed. Protect from light. Store in accordance with local regulations.

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

### 7.3. Specific End Use(s)

Beta-blocker

## 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).

| **Atenolol (29122-68-7)** | | |
|---|---|---|
| **Teva OEL** | Teva OEL (8hr-TWA) | 30 µg/m³ |
| **Acetic acid (64-19-7)** | | |
| **USA ACGIH** | ACGIH TWA (ppm) | 10 ppm |
| **USA ACGIH** | ACGIH STEL (ppm) | 15 ppm |
| **USA NIOSH** | NIOSH REL (TWA) (mg/m³) | 25 mg/m³ |
| **USA NIOSH** | NIOSH REL (TWA) (ppm) | 10 ppm |

| | | |
|---|---|---|
| **USA NIOSH** | NIOSH REL (STEL) (mg/m³) | 37 mg/m³ |
| **USA NIOSH** | NIOSH REL (STEL) (ppm) | 15 ppm |
| **USA IDLH** | US IDLH (ppm) | 50 ppm |
| **USA OSHA** | OSHA PEL (TWA) (mg/m³) | 25 mg/m³ |
| **USA OSHA** | OSHA PEL (TWA) (ppm) | 10 ppm |

### 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** : A slightly hazy, purple liquid

**Odor** : Grape odor

**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:** 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

| **Atenolol (29122-68-7)** | |
|---|---|
| **LD50 Oral Rat** | > 2000 mg/kg |

| **Citric acid (77-92-9)** | |
|---|---|
| **LD50 Oral Rat** | 5400 mg/kg |
| **LD50 Dermal Rat** | > 2000 mg/kg |

| **C.I. Acid Yellow 3 (8004-92-0)** | |
|---|---|
| **LD50 Oral Rat** | 2000 mg/kg |

| **Sodium benzoate (532-32-1)** | |
|---|---|
| **LD50 Oral Rat** | 4070 mg/kg |

| **FD and C Red No. 40 (25956-17-6)** | |
|---|---|
| **LD50 Oral Rat** | > 10000 mg/kg |
| **LD50 Dermal Rabbit** | > 10000 mg/kg |

| **Acetic acid (64-19-7)** | |
|---|---|
| **LD50 Oral Rat** | 3310 mg/kg |

| **Methyl anthranilate (134-20-3)** | |
|---|---|
| **LD50 Oral Rat** | 2910 mg/kg |
| **LD50 Dermal Rabbit** | 5000 mg/kg |
| **ATE (Dermal)** | 5,000.00 mg/kg body weight |

| **Hexanoic acid (142-62-1)** | |
|---|---|
| **LD50 Oral Rat** | 2050 µl/kg |
| **LC50 Inhalation Rat** | 2.05 mg/l/4h |

| **6-Octen-1-ol, 3,7-dimethyl-, acetate (150-84-5)** | |
|---|---|
| **LD50 Oral Rat** | 6800 mg/kg |

**Skin Corrosion/Irritation:** Not classified

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

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

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Some evidence of carcinogenicity in animal studies.

**Reproductive Toxicity:** Some evidence of reproductive toxicity in animal studies.

**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:** 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.

**Other Information:**

**Central Nervous System:** May cause: dizziness, vertigo, fatigue, insomnia, headache, depression, weakness.

**Cardiovascular System** Bronchospasm. Slow heart rate.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

### 12.2. Persistence and Degradability

| FIRST® - Atenolol 2 mg/mL (300mL) | |
|---|---|
| **Persistence and Degradability** | Not established. |

| Citric acid (77-92-9) | |
|---|---|
| **LC50 Fish 1** | 1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |

| Sodium benzoate (532-32-1) | |
|---|---|
| **LC50 Fish 1** | 420 (420 - 558) mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through]) |
| **EC50 Daphnia 1** | 650 mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| **LC50 Fish 2** | > 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) |

| Acetic acid (64-19-7) | |
|---|---|
| **LC50 Fish 1** | 79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) |
| **EC50 Daphnia 1** | 65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |
| **LC50 Fish 2** | 75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |

| Hexanoic acid (142-62-1) | |
|---|---|
| **LC50 Fish 1** | 306 - 334 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through]) |
| **LC50 Fish 2** | 88 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) |

### 12.3. Bioaccumulative Potential

| FIRST® - Atenolol 2mg/ml | |
|---|---|
| **Bioaccumulative Potential** | Not established. |

| Citric acid (77-92-9) | |
|---|---|
| **Log Pow** | -1.72 (at 20 °C) |

| Sodium benzoate (532-32-1) | |
|---|---|
| **BCF Fish 1** | (no bioaccumulation) |
| **Log Pow** | -2.13 |

| Acetic acid (64-19-7) | |
|---|---|
| **Log Pow** | -0.31 (at 20 °C) |

| Hexanoic acid (142-62-1) | |
|---|---|
| **Log Pow** | 1.88 |

**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

| |
|---|
| **Citric acid (77-92-9)** |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| |
|---|
| **C.I. Acid Yellow 3 (8004-92-0)** |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| |
|---|
| **Sodium benzoate (532-32-1)** |
| 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 |

| |
|---|
| **Water (7732-18-5)** |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| | |
|---|---|
| **Acetic acid (64-19-7)** | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| **CERCLA RQ** | 5000 lb |

| |
|---|
| **Methyl anthranilate (134-20-3)** |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| |
|---|
| **Hexanoic acid (142-62-1)** |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| |
|---|
| **6-Octen-1-ol, 3,7-dimethyl-, acetate (150-84-5)** |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

### 15.2. US State Regulations

| |
|---|
| **Acetic acid (64-19-7)** |
| U.S. - Massachusetts - Right To Know List |
| U.S. - New Jersey - Right to Know Hazardous Substance List |
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| U.S. - Pennsylvania - RTK (Right to Know) List |

| |
|---|
| **Hexanoic acid (142-62-1)** |
| 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

**Date of Preparation or Latest Revision** : 09/20/2018

**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:**

| | |
|---|---|
| Car. 2 | Carcinogen Category 2 |
| Rep. 2 | Reproductive Toxicity Category 2 |
| Lact. | Lactation - May cause harm to breast-fed children |
| H317 | May cause an allergic skin reaction |
| Acute Tox. 4 (Inhalation:dust,mist) | Acute toxicity (inhalation:dust,mist) Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral) Category 4 |
| Aquatic Acute 3 | Hazardous to the aquatic environment - Acute Hazard Category 3 |
| Aquatic Chronic 2 | Hazardous to the aquatic environment - Chronic Hazard Category 2 |
| Comb. Dust | Combustible Dust |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Flam. Liq. 3 | Flammable liquids Category 3 |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| Skin Corr. 1C | Skin corrosion/irritation Category 1C |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |

| | |
|---|---|
| H226 | Flammable liquid and vapor |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H332 | Harmful if inhaled |
| H402 | Harmful to aquatic life |
| H411 | Toxic to aquatic life with long lasting effects |

*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)