

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Substance
Product Name: FIRST® - Metoprolol 10 mg/mL
CAS-No.: Not applicable
Product Code: 220-10 (NDC 65628-220-10), 230-03 (NDC 65628-230-03)
Synonyms: Not applicable

1.2. Intended Use of the Product

Use of the Substance/Mixture: Beta-Adrenoceptor Atagonist

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

Serious eye damage/eye irritation Category 2A
 Specific target organ toxicity, single exposure Category 1 (cardiovascular system)
 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) : H305 - May be harmful if swallowed and enter airways
 H320 - Causes eye irritation

Precautionary Statements (GHS-US) : P273 – Avoid the release to the environment.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P302+P352 - If on skin: Wash with plenty of water.
 P363 - Wash contaminated clothing before reuse.

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

3.2. Mixture

Name : FIRST® - Metoprolol 10mg/mL
CAS-No. : N/A

Name	Product Identifier	%	GHS-US classification
Metoprolol Tartrate	(CAS-No.) 56392-17-7	1	STOT SE 1 (cardio. system) Eye Irrit. 2A
Water	(CAS No) 7732-18-5	98.5 – 99	Not classified

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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 Comb. Dust
Sodium benzoate	(CAS No) 532-32-1	0.09	Eye Irrit. 2A, H319 Comb. Dust
Acetic acid	(CAS No) 64-19-7	0.01 - 0.015	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 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 Skin Corr. 1C, H314 Eye Dam. 1, H318 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 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.

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: Skin sensitization.

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.

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). Nitrogen oxides. Hydrogen chloride gas. 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. 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 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)

Antibacterial 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).

Metoprolol Tartrate (56392-17-7)		
USA ACGIH	ACGIH TWA (mg/m ³)	0.1 mg/m ³
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/m ³)	25 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	10 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	37 mg/m ³
USA NIOSH	NIOSH REL (STEL) (ppm)	15 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	10 ppm

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8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains 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, 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.

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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

Metoprolol Tartrate	
LD50 Oral Rat	3090 - 4670 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: 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: 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.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

FIRST® - Metoprolol	
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])

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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® - Metoprolol	
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

FIRST® - Metoprolol	
SARA Section 311/312 Hazard Classes	Not Applicable
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	

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

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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:

Actue 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 Liquid Category 3
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Corr. 1A	Skin Corrosion Category 1A
H226	Flammable liquid and vapor
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

HMIS III Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur
Flammability : 0 Minimal Hazard
Physical : 0 Minimal Hazard

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)