

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixtures

Product Name: FIRST[®] - Baclofen 1

Product Code: 65628-100-04

Synonyms: Not applicable

1.2. Intended Use of the Product

Use of the Substance/Mixture: Muscle relaxer

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

Not classified

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation..
H335 - May cause respiratory irritation.
H336 - May cause drowsiness or dizziness.
H360 - May damage fertility or the unborn child.

Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing must not be allowed out of the workplace.
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.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P312 - Call a poison center or doctor if you feel unwell.
P330 - Rinse mouth.
P333+P313 - If skin irritation or rash 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.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

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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

Not applicable

3.2. Mixture

| Name | Product Identifier | % | GHS-US classification |
|---|---------------------|---------------|--|
| Baclofen | (CAS No) 1134-47-0 | .001 | Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1B, H360 STOT SE 3, H336 STOT SE 3, H335 Comb. Dust |
| Water | (CAS No) 7732-18-5 | 97 - 97.5 | Not classified |
| Cellulose | (CAS No) 9004-34-6 | 1.05 - 1.5 | Comb. Dust |
| Citric acid | (CAS No) 77-92-9 | 0.5 | Eye Irrit. 2A, H319 Comb. Dust |
| Sodium carboxymethyl cellulose | (CAS No) 9004-32-4 | 0.15 - 0.45 | Comb. Dust |
| Trisodium citrate dihydrate | (CAS No) 6132-04-3 | 0.2 | Comb. Dust |
| Sodium benzoate | (CAS No) 532-32-1 | 0.15 | Eye Irrit. 2A, H319 Comb. Dust |
| Xanthan gum | (CAS No) 11138-66-2 | 0.1 | Comb. Dust |
| .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 | (CAS No) 53956-04-0 | 0.05 | Not classified |
| Sodium saccharin | (CAS No) 128-44-9 | 0.03 | Not classified |
| Silica gel | (CAS No) 63231-67-4 | 0.005 - 0.025 | Not classified |
| Polyethylene glycol stearate | (CAS No) 9004-99-3 | 0.005 - 0.025 | 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: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Prolonged exposure may 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: 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.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

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 considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

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). Sodium oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

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 any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. 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

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 vapors, mist, spray.

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.

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)

Muscle relaxer

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).

| Cellulose (9004-34-6) | | |
|-----------------------|--------------------------------------|--|
| USA ACGIH | ACGIH TWA (mg/m ³) | 10 mg/m ³ |
| USA NIOSH | NIOSH REL (TWA) (mg/m ³) | 10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust) |
| USA OSHA | OSHA PEL (TWA) (mg/m ³) | 15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction) |

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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.

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 | : Little hazy, purple 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:** 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

| | |
|-----------------------|-----------|
| Baclofen (1134-47-0) | |
| LD50 Oral Rat | 145 mg/kg |
| Citric acid (77-92-9) | |

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| | |
|--|---|
| LD50 Oral Rat | 5400 mg/kg |
| LD50 Dermal Rat | > 2000 mg/kg |
| Sodium carboxymethyl cellulose (9004-32-4) | |
| LD50 Oral Rat | 27000 mg/kg |
| LD50 Dermal Rabbit | > 2000 mg/kg |
| LC50 Inhalation Rat | > 5800 mg/m ³ (Exposure time: 4 h) |
| LC50 Inhalation Rat | > 5.8 mg/l/4h |
| Cellulose (9004-34-6) | |
| LD50 Oral Rat | > 5000 mg/kg |
| LD50 Dermal Rabbit | > 2000 mg/kg |
| LC50 Inhalation Rat | > 5800 mg/m ³ (Exposure time: 4 h) |
| .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) | |
| LD50 Oral Rat | > 10 g/kg |
| Sodium saccharin (128-44-9) | |
| LD50 Oral Rat | 10000 mg/kg |
| Polyethylene glycol stearate (9004-99-3) | |
| LD50 Oral Rat | 53 ml/kg |
| Sodium benzoate (532-32-1) | |
| LD50 Oral Rat | 4070 mg/kg |
| Xanthan gum (11138-66-2) | |
| LD50 Oral Rat | > 45000 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

| | |
|------------------------------------|---|
| Sodium saccharin (128-44-9) | |
| IARC group | 3 |

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: Prolonged exposure may 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: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

| | |
|------------------------------------|--|
| Citric acid (77-92-9) | |
| LC50 Fish 1 | 1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| Sodium saccharin (128-44-9) | |
| LC50 Fish 1 | 16400 - 20400 mg/l (Exposure time: 96 h - Species: Pimephales promelas [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]) |

12.2. Persistence and Degradability

| | |
|--------------------------------------|------------------|
| FIRST® - Baclofen 1 | |
| Persistence and Degradability | Not established. |

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| | |
|--------------------------------------|---------------------------------|
| Citric acid (77-92-9) | |
| Persistence and Degradability | Readily biodegradable in water. |

12.3. Bioaccumulative Potential

| | |
|-------------------------------------|------------------|
| FIRST® - Grape II Suspension | |
| Bioaccumulative Potential | Not established. |

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

| | |
|------------------------------------|------|
| Sodium saccharin (128-44-9) | |
| Log Pow | 0.91 |

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

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.

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 | |

| | |
|---|---|
| Sodium carboxymethyl cellulose (9004-32-4) | |
| 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)). |

| | |
|---|---|
| Cellulose (9004-34-6) | |
| 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)). |

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

| | |
|---|---|
| Sodium saccharin (128-44-9) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| EPA TSCA Regulatory Flag | TP - TP - indicates a substance that is the subject of a proposed Section 4 test rule under TSCA. |

| | |
|---|--|
| 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 | |
| EPA TSCA Regulatory Flag | XU - XU - indicates a substance exempt from reporting under the |

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| | |
|---|---|
| | Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)). |
| Sodium benzoate (532-32-1) | |
| 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 | |
| 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)). |
| Water (7732-18-5) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |

15.2. US State Regulations

| | |
|---|--|
| Cellulose (9004-34-6) | |
| 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 | |
| Sodium saccharin (128-44-9) | |
| 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 | |
| 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

| | |
|--------------------------|--|
| Revision Date | : 08/31/2017 |
| 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:

| | |
|---------------|---|
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| H319 | Causes serious eye irritation |

HMIS III Rating

| | |
|---------------------|---------------------|
| Health | : 2 Moderate Hazard |
| 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)