

**SECTION 1: IDENTIFICATION**

**1.1. Product Identifier**

**Product Form:** Substance  
**Product Name:** FIRST® - Progesterone VGS 100 & 200  
**CAS-No.:** Not applicable  
**Product Code:** 062-01, 063-01  
**Synonyms:** NDC # 65628-062-01, NDC # 65628-063-01

**1.2. Intended Use of the Product**

**Use of the Substance/Mixture:** Hormone

**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**

Carc. 1B	H350
Repr. 1A	H360
Lact.	H362
Comb. Dust	

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)**

: Danger

**Hazard Statements (GHS-US)**

: H350 - May cause cancer.  
H360 - May damage fertility or the unborn child.  
H362 - May cause harm to breast-fed children.  
H317 - May cause an allergic skin reaction.  
H401 - Toxic to aquatic life.  
H412 - Harmful to aquatic life with long lasting effects.

**Precautionary Statements (GHS-US)**

: P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe vapors, mist, or spray.  
P263 - Avoid contact during pregnancy/while nursing.  
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves, protective clothing, and eye protection.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
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

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## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Name : FIRST® - Progesterone VGS 100 & 200

CAS-No. : Not applicable

Name	Product Identifier	%	GHS-US classification
Progesterone	(CAS-No.) 57-83-0	< 100	Carc. 1B, H350 Lact., H362 Repr. 1A, H360 Comb. Dust
Water	(CAS-No.) 7732-18-5	< 100	Not classified
Stearic acid	(CAS-No.) 57-11-4	< 100	Comb. Dust
Glyceryl monostearates (covers both 1-stearoylglycerol and 2-stearoylglycerol)	(CAS-No.) 31566-31-1	< 100	Comb. Dust
Triethanolamine	(CAS-No.) 102-71-6	< 100	Not classified
Isopropyl myristate	(CAS-No.) 110-27-0	< 100	Aquatic Acute 3, H402
Sorbitan monooctadecanoate	(CAS-No.) 1338-41-6	< 100	Not classified
Polyoxyethylene sorbitan monostearate	(CAS-No.) 9005-67-8	< 100	Not classified
Mixture, 1-octadecanol with 1-hexadecanol	(CAS-No.) 8005-44-5	< 100	Not classified
Dimethyl silicone	(CAS-No.) 9006-65-9	< 100	Not classified
Petrolatum	(CAS-No.) 8009-03-8	< 100	Not classified
Alcohols, lanolin	(CAS-No.) 8027-33-6	< 100	Not classified
Urea, N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)-	(CAS-No.) 39236-46-9	< 100	Comb. Dust Skin Sens. 1B, H317 Aquatic Acute 2, H401
Benzoic acid, 4-hydroxy-, methyl ester	(CAS-No.) 99-76-3	< 100	Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust
Propyl 4-hydroxybenzoate	(CAS-No.) 94-13-3	< 100	Aquatic Acute 2, H401 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:** May cause cancer. May damage fertility. May damage the unborn child. May cause harm to breast-fed children.

**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:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** May cause cancer. May damage fertility or the unborn child.

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## 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>).

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

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not get in eyes, on skin, or on clothing. Do not breathe dust. 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:** Avoid contact during pregnancy/while nursing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. 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.

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

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## 7.3. Specific End Use(s)

Hormone

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

Stearic acid (57-11-4)		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> (inhalable particulate matter) 3 mg/m <sup>3</sup> (respirable particulate matter)
Triethanolamine (102-71-6)		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>

### 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.

#### Consumer Exposure Controls

: Avoid contact during pregnancy/while nursing.

#### 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	: Varies in color
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

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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:** Not available

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

<b>Stearic acid (57-11-4)</b>	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
<b>Triethanolamine (102-71-6)</b>	
LD50 Oral Rat	6400 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
<b>Isopropyl myristate (110-27-0)</b>	
LD50 Oral Rat	> 10000 mg/kg
LD50 Dermal Rabbit	5 g/kg
LC50 Inhalation Rat	> 41 mg/l (Exposure time: 1 h)
<b>Sorbitan monooleate (1338-41-6)</b>	
LD50 Oral Rat	31 g/kg
<b>Polyoxyethylene sorbitan monostearate (9005-67-8)</b>	
LD50 Oral Rat	> 60 ml/kg
<b>Petrolatum (8009-03-8)</b>	
LD50 Dermal Rabbit	3600 mg/kg
<b>Urea, N,N'-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]- (39236-46-9)</b>	
LD50 Oral Rat	> 8000 mg/kg
LD50 Dermal Rabbit	> 8000 mg/kg
<b>Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)</b>	
LD50 Oral Rat	2100 mg/kg
<b>Propyl 4-hydroxybenzoate (94-13-3)</b>	
LD50 Oral Rat	> 5000 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:** May cause cancer.

<b>Progesterone (57-83-0)</b>	
IARC group	2B
National Toxicology Program (NTP) Status	Reasonably anticipated to be Human Carcinogen.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.
<b>Triethanolamine (102-71-6)</b>	
IARC group	3

**Reproductive Toxicity:** May damage fertility or the unborn child. May cause harm to breast-fed children. (This material or its emissions may appear in breast milk of nursing mothers.)

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**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:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** May cause cancer. May damage fertility or the unborn child.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

Triethanolamine (102-71-6)	
LC50 Fish 1	10600 (10600 - 13000) mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
LC50 Fish 2	1000 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
ErC50 (Algae)	169 mg/l
Isopropyl myristate (110-27-0)	
LC50 Fish 1	8400 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
EC50 Daphnia 1	100 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	8400 mg/l (Exposure time: 96 h - Species: Brachydanio rerio)
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LC50 Fish 1	59.5 mg/l (Exposure time: 96 h - Species: Oryzias latipes)
EC50 Daphnia 1	11.2 mg/l
ErC50 (Algae)	91 mg/l
NOEC Chronic Crustacea	0.2 mg/l (Species: Daphnia magna)
NOEC Chronic Algae	20 mg/l
Propyl 4-hydroxybenzoate (94-13-3)	
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

### 12.2. Persistence and Degradability

FIRST® - Progesterone VGS 100 & 200 (57-83-0)	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

FIRST® - Progesterone VGS 100 & 200 (57-83-0)	
Bioaccumulative Potential	Not established.
Triethanolamine (102-71-6)	
BCF Fish 1	3.9
Log Pow	-2.53
Isopropyl myristate (110-27-0)	
Log Pow	> 6
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Bioconcentration Factor (BCF REACH)	6.4
Log Pow	1.98

### 12.4. Mobility in Soil

Stearic acid (57-11-4)	
Log Koc	51.05

### 12.5. Other Adverse Effects

**Other Information** : Avoid release to the environment.

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## 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>FIRST® - Progesterone VGS 100 &amp; 200 (57-83-0)</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Delayed (chronic) health hazard Fire hazard Sudden release of pressure hazard
<b>Progesterone (57-83-0)</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>Stearic acid (57-11-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Glyceryl monostearates (covers both 1-stearoylglycerol and 2-stearoylglycerol) (31566-31-1)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Triethanolamine (102-71-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Isopropyl myristate (110-27-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Sorbitan monoctadecanoate (1338-41-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Polyoxyethylene sorbitan monostearate (9005-67-8)</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>Petrolatum (8009-03-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Alcohols, lanolin (8027-33-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Urea, N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]- (39236-46-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)</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	

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## 15.2. US State Regulations

<b>Progesterone (57-83-0)</b>	
<b>U.S. - California - Proposition 65 - Carcinogens List</b>	WARNING: This product contains chemicals known to the State of California to cause cancer.
<b>Progesterone (57-83-0)</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) - Special Hazardous Substances	
U.S. - Pennsylvania - RTK (Right to Know) List	
<b>Triethanolamine (102-71-6)</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:

Carc. 1B	Carcinogenicity Category 1B
Comb. Dust	Combustible Dust
Lact.	Reproductive toxicity (Lact.)
Repr. 1A	Reproductive toxicity Category 1A
H350	May cause cancer
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children

*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)