

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Hydroxyprogesterone Caproate Injection, USP

Product Code: NDC 0517-1767-01 (single pack)

1.2. Intended Use of the Product

Use of the Substance/Mixture: Hydroxyprogesterone caproate injection is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. For intramuscular use only.

Limitation of use: Hydroxyprogesterone caproate injection is not intended for use in women with multiple gestations or other risk factors for preterm birth.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Luitpold Pharmaceuticals, Inc.

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

www.luitpold.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Skin Irrit. 2 H315

Eye Irrit. 2B H320

Carc. 2 H351

Repr. 1B H360

Aquatic Acute 1 H400

Aquatic Chronic 2 H411

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)

: H315 - Causes skin irritation.
 H320 - Causes eye irritation.
 H351 - Suspected of causing cancer.
 H360 - May damage fertility or the unborn child.
 H400 - Very toxic to aquatic life.
 H411 - Toxic 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.
 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
 P273 - Avoid release to the environment.
 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.
 P321 - Specific treatment (see section 4 on this SDS).
 P332+P313 - If skin irritation occurs: Get medical advice/attention.
 P337+P313 - If eye irritation persists: Get medical advice/attention.

Hydroxyprogesterone Caproate Injection, USP

Safety Data Sheet

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

P362+P364 - Take off contaminated clothing and wash it before reuse.

P391 - Collect spillage.

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

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Benzyl benzoate	(CAS-No.) 120-51-4	45 - 50	Acute Tox. 4 (Oral), H302 Aquatic Acute 1, H400 Aquatic Chronic 2, H411
Castor oil	(CAS-No.) 8001-79-4	25 - 31	Skin Irrit. 2, H315 Eye Irrit. 2B, H320
Hydroxyprogesterone caproate	(CAS-No.) 630-56-8	25	Carc. 2, H351 Repr. 1B, H360

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 Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

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: Causes eye irritation. Causes skin irritation. Suspected of causing cancer. May damage fertility. May damage the unborn child.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: May cause moderate irritation, including burning sensation, tearing, redness or swelling.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of causing cancer. May damage fertility or the unborn child.

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: 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). Irritating fumes.

Hydroxyprogesterone Caproate Injection, USP

Safety Data Sheet

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

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

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 vapor, mist or 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. Avoid release to the environment. Collect spillage.

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

Additional Hazards When Processed: Handle in accordance with standard industrial practices, and ensure appropriate usage.

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. Obtain special instructions before use.

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. Store at 20° to 25°C (68° to 72°F) [See USP Controlled Room Temperature]. Do not refrigerate or freeze. Caution: Protect vial from light. Store vial in its box. Store upright.

Incompatible Materials: Strong acids, strong bases, strong oxidizers and reducing agents.

7.3. Specific End Use(s)

Hydroxyprogesterone caproate injection is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. For intramuscular use only.

Limitation of use: Hydroxyprogesterone caproate injection is not intended for use in women with multiple gestations or other risk factors for preterm birth.

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).

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. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Hydroxyprogesterone Caproate Injection, USP

Safety Data Sheet

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

- 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** : Clear, Yellow, Sterile, Non-Pyrogenic Solution
- 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)** : Not applicable
- Vapor Pressure** : No data available
- Relative Vapor Density at 20°C** : No data available
- Relative Density** : No data available
- Specific Gravity** : 1.066 (Water = 1)
- 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 and reducing agents.
- 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

Benzyl benzoate (120-51-4)	
LD50 Oral Rat	1700 mg/kg
LD50 Dermal Rabbit	4000 mg/kg

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes eye irritation.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Suspected of causing cancer.

Hydroxyprogesterone caproate (630-56-8)	
IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: May damage fertility or the unborn child.

Hydroxyprogesterone Caproate Injection, USP

Safety Data Sheet

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

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: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: May cause moderate irritation, including burning sensation, tearing, redness or swelling.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Suspected of causing cancer. May damage fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Benzyl benzoate (120-51-4)	
LC50 Algae	0.475 mg/L
EC50 Daphnia 1	3.09 mg/L
NOEC Chronic Fish	0.168 mg/L QSAR (Reliability: 2)

12.2. Persistence and Degradability

Hydroxyprogesterone Caproate Injection, USP	
Persistence and Degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative Potential

Hydroxyprogesterone Caproate Injection, USP	
Bioaccumulative Potential	Not established.

Benzyl benzoate (120-51-4)	
Log Pow	3.97

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. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

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

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCES, LIQUID, N.O.S., (CONTAINS BENZYL BENZOATE)

Hazard Class : 9

Identification Number : UN3082

Label Codes : 9

Packing Group : III

Marine Pollutant : Marine pollutant

ERG Number : 171



14.2. In Accordance with IMDG

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCES, LIQUID, N.O.S., (CONTAINS BENZYL BENZOATE)

Hazard Class : 9

Identification Number : UN3082

Packing Group : III

Label Codes : 9

Hydroxyprogesterone Caproate Injection, USP

Safety Data Sheet

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

EmS-No. (Fire) : F-A

EmS-No. (Spillage) : S-F



Marine Pollutant : Marine pollutant

14.3. In Accordance with IATA

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCES, LIQUID, N.O.S., (CONTAINS BENZYL BENZOATE)

Packing Group : III

Identification Number : UN3082

Hazard Class : 9

Label Codes : 9

ERG Code (IATA) : 9L



SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Hydroxyprogesterone Caproate Injection, USP	
SARA Section 311/312 Hazard Classes	Health hazard - Serious eye damage or eye irritation Health hazard - Acute toxicity (any route of exposure) Health hazard - Carcinogenicity Health hazard - Reproductive toxicity Health hazard - Skin corrosion or Irritation
Benzoic acid (120-107-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Castor oil (8001-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

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

Date of Preparation or Latest Revision	: 06/19/2018
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:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Repr. 1B	Reproductive toxicity Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
H302	Harmful if swallowed
H315	Causes skin irritation
H320	Causes eye irritation
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child
H400	Very toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects

Hydroxyprogesterone Caproate Injection, USP

Safety Data Sheet

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

Refer to Luitpold/American Regent prescribing information for further information at:

<http://www.americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)