

## SAFETY DATA SHEET

Preparation Date: 07/23/2019

Revision date 07/23/2019

Revision Number: G1

### 1. IDENTIFICATION

#### Product identifier

**Product code:** H1234  
**Product Name:** HYDROXYPROGESTERONE CAPROATE, USP

#### Other means of identification

##### Synonyms:

Corlutin L.A.  
 NSC-17592  
 17-((1-Oxoheptyl)oxy)pregn-4-ene-3,20-dione  
 Depo-Proluton  
 Gesterol L.A.  
 17-alpha-Hexanoyloxyprog-4-ene-3,20-dione  
 Hormofort  
 HPC  
 17-Hydroxypregn-4-ene-3,20-dione hexanoate  
 Hydroxyprogesterone caproate  
 17-alpha-Hydroxyprogesterone caproate  
 17-alpha-Hydroxy progesterone n-caproate  
 17-alpha-Hydroxyprogesterone hexanoate  
 Hyproval-PA  
 Idrogestene  
 Lutate  
 Luteocrin depot  
 Lutopron  
 Pregn-4-ene-3,20-dione, 17-((1-oxoheptyl)oxy)-  
 Primolut depot  
 Progesterone caproate  
 Progesterone retard pharlon  
 Proluton depot  
 Syngynon  
 Teralutil  
**CAS #:** 630-56-8  
**RTECS #** TU5085000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** No information available.  
**Uses advised against** No information available

#### Supplier:

Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

#### Order Online At:

<https://www.spectrumchemical.com>

#### Emergency telephone number

Chemtrec 1-800-424-9300

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**Contact Person:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

## 2. HAZARDS IDENTIFICATION

### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Reproductive toxicity	Category 2
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### Label elements

#### Warning

#### Hazard statements

Suspected of damaging fertility or the unborn child



### Hazards not otherwise classified (HNOC)

Not Applicable

### Other hazards

Not available

### Precautionary Statements - Prevention

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Use personal protective equipment as required

### Precautionary Statements - Response

*IF exposed or concerned: Get medical attention*

### Precautionary Statements - Storage

Store locked up

### Precautionary Statements - Disposal

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Hydroxyprogesterone Caproate	630-56-8	100

## 4. FIRST AID MEASURES

### First aid measures

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**General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

**Most important symptoms and effects, both acute and delayed**

**Symptoms**

- May cause eye/skin irritation
- May cause respiratory irritation
- May cause digestive (gastrointestinal) tract irritation
- May affect the liver
- May affect behavior/central nervous system
- It may affect metabolism
- May cause breast tenderness or discomfort
- May cause hot flashes
- May cause loss of sexual interest or ability
- Thirst
- Frequent urge to urinate
- Abdominal discomfort, nausea, vomiting, cramping
- Dizziness
- Headache
- Insomnia
- tiredness
- May cause loss of appetite

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** The product is not flammable. If it is involved in a fire, extinguish the fire using an agent suitable for the type of surrounding fire.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous combustion products** Carbon monoxide. Carbon dioxide (CO2).

**Specific hazards** May be combustible at high temperatures.

## Special Protective Actions for Firefighters

**Specific Methods:** No information available

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid dust formation.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

**Safe Handling Advice:**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

**Technical Measures/Storage Conditions:**

Sensitive to light. Store in light-resistant containers. Store at 25 °C. Keep container tightly closed in a dry and well-ventilated place. Store away from incompatible materials.

**Incompatible Materials:**

Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### National occupational exposure limits

##### United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Hydroxyprogesterone	630-56-8	None	None	None	None

Caproate					
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### Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Hydroxyprogesterone Caproate	630-56-8	None	None	None	None

### Australia and Mexico

Component	CAS No	Australia	Mexico
Hydroxyprogesterone Caproate	630-56-8	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

- Eye protection:** Goggles or Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing  
Chemical resistant apron  
Gloves
- Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical state:

Solid

#### Appearance:

Crystalline powder.

#### Color:

White to Off-White.

#### Odor:

No information available.

#### Taste

No information available.

#### Formula

C27H40O4

#### Molecular/Formula weight (g/mole):

428.60

#### Flammability (solid, gas)

no data available

#### Flashpoint (°C/°F):

No information available

#### Flash Point Tested according to:

Not available

#### Autoignition Temperature (°C/°F):

No information available

#### Lower Explosion Limit (%):

No information available

#### Upper Explosion Limit (%):

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No information available

**Melting point/range(°C/°F):**  
119-121°C/ 246.2-249.8°F

**Decomposition temperature(°C/°F):**  
No information available

**Boiling point/range(°C/°F):**  
No information available

**Bulk density:**  
No information available

**Density (g/cm3):**  
No information available

**Specific gravity:**  
No information available

**pH**  
No information available

**Vapor pressure @ 20°C (kPa):**  
No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
No information available

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Soluble in Ether  
Freely soluble in alcohol  
Slightly soluble in Benzene  
Very soluble in chloroform

## 10. STABILITY AND REACTIVITY

### Reactivity

No information available

### Chemical stability

**Stability:** Sensitive to light. Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Ignition sources. Exposure to light. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents

**Hazardous decomposition products:** Carbon oxides.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Skin. Liver. Ingestion. Eyes.

### Acute Toxicity

### Component Information

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Hydroxyprogesterone Caproate	
CAS No	630-56-8

**LD50/oral/rat** = No information available  
**LD50/oral/mouse** = No information available  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

**Product Information**

**LD50/oral/rat** =  
**Value - Acute Toxicity** = No information available

**LD50/oral/mouse** =  
**Value - Acute Tox** = No information available

**LD50/dermal/rabbit**  
**Value - Acute Toxicity** = No information available

**LD50/dermal/rat**  
**VALUE - Acute Tox** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor** = No information available  
**VALUE - Gas** = No information available  
**VALUE - Dust/Mist** = No information available

**Symptoms**

**Skin Contact:** May cause skin irritation.  
**Eye Contact:** May cause eye irritation.  
**Inhalation** May cause irritation of respiratory tract.  
**Ingestion** Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May affect behavior/central nervous system (dizziness, headache). May affect liver. May cause loss of appetite. May cause dry mouth, thirst. May cause abdominal pain. May cause swelling of the ankles, feet, legs.  
**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** No information available.  
**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Hydroxyprogesterone Caproate	630-56-8	Supplement 7 [1987] Progestins	Not listed	Not listed	Present	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** Suspected of damaging fertility or the unborn child

**Reproductive Effects:** Possible risk of impaired fertility  
**Developmental Effects:** Possible risk of harm to the unborn child  
**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** Reproductive System.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** Aquatic environment.  
**Persistence and degradability:** No information available  
**Bioaccumulative potential:** No information available.  
**Mobility in soil** No information available  
**Other adverse effects** No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Waste from residues / unused products:**  
Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**  
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series	RCRA - K Series	RCRA - P Series	RCRA - U Series
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		Wastes	Wastes	Wastes	Wastes
Hydroxyprogesterone Caproate	630-56-8	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

### TDG (Canada)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

### ADR

**UN Number** Not regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Packing group** No information available  
**Subsidiary Risk:** No information available

### IMDG

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

### RID

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available

### ICAO (air)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available

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**Packing Group:** No information available

**IATA**

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** No information available  
**Special Provisions** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Hydroxyprogesterone Caproate	630-56-8	Not Listed	Not present	Present	Present (9)-288	Not listed	Present	Present 211-138-8

**U.S. Regulations**

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Hydroxyprogesterone Caproate	630-56-8	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Hydroxyprogesterone Caproate	630-56-8	None	None	None	None	None

**U.S. TSCA**

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Hydroxyprogesterone Caproate	630-56-8	Not Applicable	Not Applicable

**Canada**

**WHIMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Hydroxyprogesterone Caproate	630-56-8	Not Listed	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Hydroxyprogesterone Caproate	630-56-8	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Hydroxyprogesterone Caproate	630-56-8	Not listed

#### EU Classification

##### EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Hydroxyprogesterone Caproate	630-56-8	

##### EU - CLP (1272/2008)

#### R-phrases(s)

R60 - May impair fertility

R61 - May cause harm to the unborn child

#### S-phrases(s)

S53 - Avoid exposure - obtain special instructions before use

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Hydroxyprogesterone Caproate	630-56-8		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

#### Indication of danger:

T - Toxic

T



## 16. OTHER INFORMATION

**Preparation Date:** 07/23/2019  
**Revision date** 07/23/2019  
**Prepared by:** Sonia Owen

**Disclaimer:** All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**