SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME PROGESTERONE, USP (Wettable)
PRODUCT CODE 0057
SUPPLIER MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
MEDISCA Australia PTY LTD
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Rickety Street, Mascot, NSW 2020
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126
EMERGENCY PHONE
USES Hormone

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 5)
Toxic to Reproduction (Category 1B)
Carcinogenicity (Category 1B)

PICTOGRAM

SIGNAL WORD Danger

HAZARD STATEMENT(S)
Harmful if swallowed.
May damage fertility or the unborn child.
May cause cancer.

AUSTRALIA-ONLY HAZARDS
Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing, eye protection, face protection.
Avoid release to the environment.
Response IF EXPOSED OR CONCERNED: Get medical advice/attention.
Storage Store locked up.
Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
Health Hazard 2 Flammability 0 Reactivity 0 Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME: Pregn-4-ene-3, 20-Dione  
BOTANICAL NAME: Not applicable  
SYNONYM: Corpus luteum hormone  
CHEMICAL FORMULA: C_{21}H_{30}O_2  
CAS NUMBER: 57-83-0  
MOLECULAR WEIGHT: 314.5  
COMPOSITION:  

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROGESTERONE</td>
<td>57-83-0</td>
<td>&gt; 98</td>
</tr>
<tr>
<td>SODIUM LAURYL SULFONATE</td>
<td>2386-53-0</td>
<td>&lt; 2</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

Chemical family: Steroid.

Wettable progesterone is treated with Sodium Lauryl Sulfonate for easy water/hydroalcoholic dispersion. It is used in the preparation of liquid dispersion (suspensions), it may be used to compound topical preparations.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Fine dust clouds may form explosive mixtures with air.

FLAMMABLE PROPERTIES: May be combustible at high temperature.

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.
CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15° and 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: PROGESTERONE    CAS #: 57-83-0

<table>
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<tr>
<th>osl</th>
<th>osh</th>
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<th>safe work australia hsis</th>
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</table>

Chemical Name: SODIUM LAURYL SULFONATE    CAS #: 2386-53-0

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<th>acgih tlv</th>
<th>niosh</th>
<th>aiha weel</th>
<th>safe work australia hsis</th>
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<td>remarks</td>
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</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.
NOTES
Progesterone: USP: ELV: Industrial use: STEL: 0.1 mg/m³; TWA: 12.5 micrograms/m³
Progesterone: Manufacturer: OEL: TWA: 8hr: 30 micrograms/m³ (skin)

Progesterone is a potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PHYSICAL STATE</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td>White or creamy white, crystalline powder. Is stable in air.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Practically insoluble in water; soluble in alcohol, acetone and dioxane; sparingly soluble in vegetable oils.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>pH</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>MELTING POINT</td>
<td>128-131°C, 262.4-267.8°F</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>FREEZING POINT</td>
<td>128-131°C, 262.4-267.8°F</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
<td>1.17 (23°C)</td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
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</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>3.87</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>Not available</td>
</tr>
</tbody>
</table>

NOTES
The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

| REACTIVITY | Not established. |
| STABILITY   | Stable under recommended storage conditions. |
| MATERIALS TO AVOID | Strong oxidizing agents. Alkaline metals. Peroxides. |
| HAZARDOUS DECOMPOSITION PRODUCTS | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur. |
| HAZARDOUS POLYMERIZATION | Will not occur. |
| POSSIBILITY OF HAZARDOUS REACTION | Not established. |
| CONDITIONS TO AVOID | Moisture, sunlight and extreme temperatures. |
### SAFETY DATA SHEET

**SECTION 11: TOXICOLOGICAL INFORMATION**

#### ACUTE TOXICITY

**PROGESTERONE:**
- Oral: Rat: LD50: (mg/kg): > 5000
- Dermal: Rabbit LD50: (mg/kg): Not available
- Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SODIUM LAURYL SULFONATE:**
- Oral: Rat: LD50: (mg/kg): Not available
- Dermal: Rabbit LD50: (mg/kg): Not available
- Inhalation: Rat: LC50: (mg/L/4hr): Not available

#### SKIN CORROSION/IRRITATION
Due to lack of data the classification is not possible.

#### SERIOUS EYE DAMAGE/EYE IRRITATION
Due to lack of data the classification is not possible.

#### RESPIRATORY OR SKIN SENSITIZATION
Due to lack of data the classification is not possible.

#### GERM CELL MUTAGENICITY
Based on available data, the classification criteria are not met.

#### CARCINOGENICITY

<table>
<thead>
<tr>
<th>Agency</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OSHA</strong></td>
<td>PROGESTERONE is listed. SODIUM LAURYL SULFONATE is not listed.</td>
</tr>
<tr>
<td><strong>NTP</strong></td>
<td>PROGESTERONE is reasonably anticipated to be a human carcinogen. SODIUM LAURYL SULFONATE is not listed.</td>
</tr>
<tr>
<td><strong>IARC</strong></td>
<td>PROGESTERONE is listed in group 2b (possibly carcinogenic to humans). SODIUM LAURYL SULFONATE is not evaluated.</td>
</tr>
<tr>
<td><strong>California Proposition 65</strong></td>
<td>This product contains the following chemical known to the State of California to cause cancer: PROGESTERONE. No other component of this product, present at ≥0.1% is known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td>
</tr>
</tbody>
</table>

#### ADDITIONAL CARCINOGENICITY INFORMATION

**Suspected of causing cancer.**

**PROGESTERONE:**
- 0.059 - 0.9 mg/day Carcinogenicity; Result: Increased incidence of ovarian granulosa cell tumors.; Species: Mouse; Test Duration: 18 months

Carcinogenicity Result: Earlier onset of breast carcinomas and higher incidence in mice with tumor virus.; Species: Mouse; Test Duration: 104 weeks

#### REPRODUCTIVE TOXICITY
May damage fertility or the unborn child.

For progestins: Exposure during early pregnancy may lead to chromosomal abnormalities and congenital malformations, including genital abnormalities.

**0.25 - 0.5 mg Gestational study**
- Result: Reproductive abnormalities in offspring. Species: Mouse

**30 mg/kg Gestational study**
- Result: Reproductive abnormalities in offspring. Species: Rabbit

**5 mg/kg Developmental**
- Result: Reduced birth weights, increased incidence of resorptions, and developmental defects. Species: Rat

#### SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Due to lack of data the classification is not possible.

#### SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Based on available data, the classification criteria are not met.
ASPIRATION HAZARDS
Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE
Symptoms related to the physical, chemical, and toxicological characteristics:

Delayed and immediate effects of exposure:

Medical conditions aggravated by exposure:
Progestins: Known or suspected cancer. Liver disease. Pregnancy. Thrombophlebitis or thromboembolic disease.

POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Harmful if swallowed. May cause gastrointestinal disturbances, changes in appetite or weight, fluid retention.</td>
</tr>
<tr>
<td>Skin</td>
<td>Harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation.</td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
LC50: 96 Hr: Fish: (mg/L): Not available
EC50: 48 Hr: Crustacea: (mg/L): Not available
EC50: 72 or 96Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Biodegradation (regular, non wettable form): 90%

BIOACCUMULATIVE POTENTIAL
High: LogPow: 3.87 (regular, non wettable form)

MOBILITY IN SOIL
Regular, non wettable form:
Practically insoluble in water.
Water Solubility: 8.81 mg/L (25°C)
Vapor Pressure: 1.30E-06 mm Hg (25°C)
Henry's Law Constant: 6.49E-08 atm-m³/mole (25°C)

OTHER ADVERSE EFFECTS
This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME
Not dangerous good

UN NUMBER
Not applicable

CLASS
Not applicable

PACKING GROUP
Not applicable
## AUSTRALIA

<table>
<thead>
<tr>
<th>UN PROPER SHIPPING NAME</th>
<th>Not dangerous good</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN NUMBER</td>
<td>Not applicable</td>
</tr>
<tr>
<td>CLASS</td>
<td>Not applicable</td>
</tr>
<tr>
<td>PACKING GROUP</td>
<td>Not applicable</td>
</tr>
<tr>
<td>HAZCHEM</td>
<td>Not applicable</td>
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<tr>
<td>ENVIRONMENTAL HAZARDS</td>
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</tr>
<tr>
<td>SPECIAL SHIPPING INFORMATION</td>
<td>Not applicable</td>
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</tbody>
</table>

## SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.85</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
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<tbody>
<tr>
<td>SODIUM LAURYL SULFONATE 2386-53-0</td>
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<td>PROGESTERONE 57-83-0</td>
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<td>X</td>
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N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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<tr>
<td>SODIUM LAURYL SULFONATE 2386-53-0</td>
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<td>N/L</td>
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<tr>
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## SECTION 16: OTHER INFORMATION

### REFERENCES

Available upon request

### ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

### LAST REVISION

06/2018

### SUPERSEDES

11/2015
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.