SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
PROGESTERONE, USP (Micronized)

PRODUCT CODE
0043

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 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126

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 1
Reactivity 0
Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
SAFETY DATA SHEET

Pregn-4-ene-3, 20-Dione

Corpus luteum hormone

C₂₁H₃₀O₂

57-83-0

Not applicable

Not applicable

314.5

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.

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.
SAFETY DATA SHEET

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

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

<table>
<thead>
<tr>
<th>Chemical Name: PROGESTERONE</th>
<th>CAS #: 57-83-0</th>
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<tbody>
<tr>
<td>OSHA PEL</td>
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<tr>
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<td>HSE</td>
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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
USP: ELV: Industrial use: STEL: 0.1 mg/m³; TWA: 12.5 micrograms/m³
Manufacturer: OEL: TWA: 8hr: 30 micrograms/m³ (skin)

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE Solid
DESCRIPTION White or creamy white, crystalline powder. Is stable in air.
SAFETY DATA SHEET

SOLUBILITY
Practically insoluble in water; soluble in alcohol, acetone and dioxane; sparingly soluble in vegetable oils.

ODOR
Odorless

FLAMMABILITY
May be combustible at high temperature

ODOR THRESHOLD
Not available

PH
Not available

MELTING POINT
(126-131)°C, (258.8-267.8)°F

BOILING POINT
Not available

FREEZING POINT
(126-131)°C, (258.8-267.8)°F

FLASH POINT
>93.3°C, >199.9°F (closed cup)

SPECIFIC GRAVITY
1.17 (23°C)

EVAPORATION RATE
Not available

EXPLOSIVE LIMIT
Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)
Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)
Not available

VAPOR DENSITY
Not available

RELATIVE DENSITY
(WATER = 1)
Not available

 log P
(OCTANOL-WATER)
3.87

AUTO-IGNITION TEMPERATURE
Not available

DECOMPOSITION TEMPERATURE
Not available

VISCOITY
Not available

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

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

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY
Oral: Rat: LD50: (mg/kg): >5000
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.
SAFETY DATA SHEET

CARCINOGENICITY

OSHA
PROGESTERONE is listed.

NTP
PROGESTERONE is reasonably anticipated to be a human carcinogen.

IARC
PROGESTERONE is listed in group 2b (possibly carcinogenic to humans).

California Proposition 65
This product contains the following chemical known to the State of California to cause cancer: PROGESTERONE

ADDITIONAL CARCINOGENICITY INFORMATION

Suspected of causing cancer.

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
Due to lack of data the classification is not possible.

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

Inhalation
Harmful if inhaled. May cause respiratory tract irritation.

Ingestion
Harmful if swallowed. May cause gastrointestinal disturbances, changes in appetite or weight, fluid retention.

Skin
Harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.

Eyes
May cause eye irritation.
SECTION 12: ECOLOGICAL INFORMATION

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

PERSISTENCE AND DEGRADABILITY
- Not available

BIOACCUMULATIVE POTENTIAL
- High: LogPow: 3.87

MOBILITY IN SOIL
- 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
- Not available
- 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
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable
- HAZCHEM: Not applicable
- ENVIRONMENTAL HAZARDS: Not available
- SPECIAL SHIPPING INFORMATION: Not applicable

SECTION 15: REGULATORY INFORMATION

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Last Revision: 05/2018
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>
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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
05/2018

SUPERSEDES
04/2015

DISCLAIMER

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.