


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	PROGESTERONE, USP (Wetable)
PRODUCT CODE	0057
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 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 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

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)	May be harmful if swallowed. May damage fertility or the unborn child. May cause cancer.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S)	Not Applicable.
	Prevention <ul style="list-style-type: none"> Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Avoid release to the environment
	Response <ul style="list-style-type: none"> IF EXPOSED OR CONCERNED: Get medical advice/attention. IF SWALLOWED: Get medical help.

HMIS CLASSIFICATION	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	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
CHEMICAL FAMILY	Steroid
CAS NUMBER	57-83-0
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	314.5
COMPOSITION	

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
PROGESTERONE	57-83-0	200-350-6	> 98
SODIUM LAURYL SULFONATE	2386-53-0	219-200-6	< 2

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.

NOTES	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.
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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	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	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.
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FLAMMABLE PROPERTIES

May be combustible at high temperature.

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE 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.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

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 unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

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 unlabeled 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.

Store at 25°C. Short term excursions, temperature excursions as experienced during shipping and warehousing, are permitted between 15° and 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	68:32 progestins	IARC Group 2B; NTP: Reasonably Anticipated To Be Human Carcinogen
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

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

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

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. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

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

PHYSICAL STATE	Solid				
DESCRIPTION	White or creamy white, crystalline powder. Is stable in air.				
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				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	3.87	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	128-131°C, 262.4-267.8°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	1.17 (23°C)	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	0.0000004 kPa (25°C)	VISCOSITY	Not available

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	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.

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 SENSITIZATION

Due to lack of data the classification is not possible.

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

OSHA PROGESTERONE is listed.
 SODIUM LAURYL SULFONATE is not listed.

NTP PROGESTERONE is reasonably anticipated to be a human carcinogen.
 SODIUM LAURYL SULFONATE is not listed.

IARC PROGESTERONE is listed in group 2b (possibly carcinogenic to humans).
 SODIUM LAURYL SULFONATE is not evaluated.

**California
Proposition** 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.

**ADDITIONAL CARCINOGENICITY
INFORMATION**

Suspected of causing cancer.

REPRODUCTIVE TOXICITY

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

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
ASPIRATION HAZARDS
SIGNS AND SYMPTOMS OF
EXPOSURE**

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

ROUTES OF EXPOSURE:

Inhalation, skin, eye, ingestion

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

For progestins: Hepatitis. Porphyria. Blood clots. Jaundice. Cancer. Menstrual abnormalities. Hyperglycemia. Hypertension.

Symptoms related to the physical, chemical, and toxicological characteristics:

For progestins: Abnormal uterine bleeding. Breast enlargement, pain, or tenderness. Unexpected or increased flow of breast milk. Hot flashes. Loss of sexual desires. Dry mouth. Unusual thirst. Frequent urination. Abdominal pain. Cramping. Nausea. Loss of appetite. Dizziness. Headache. Mood changes. Insomnia. Unusual tiredness or weakness. Swelling in ankles or feet. Unusual or rapid weight gain. Skin rash. Acne. Loss or gain of hair. Brown spots on skin. Sudden changes in vision.

Medical conditions aggravated by exposure:

Progestins: Known or suspected cancer. Liver disease. Pregnancy. Thrombophlebitis or thromboembolic disease.

POTENTIAL HEALTH EFFECTS
Inhalation

May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion

May be harmful if swallowed. May cause gastrointestinal disturbances, changes in appetite or weight, fluid retention.

Skin

May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.

Eyes

May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

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

Not available

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

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

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

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME Not dangerous good
UN NUMBER Not applicable
CLASS Not applicable
PACKING GROUP Not applicable

AUSTRALIA

HAZCHEM Not applicable

EU

**TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE** Not listed

ENVIRONMENTAL HAZARDS Not available
**SPECIAL SHIPPING
INFORMATION** Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
SODIUM LAURYL SULFONATE 2386-53-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L
PROGESTERONE 57-83-0	N/L	N/L	N/L	N/L	N/L	X	X	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
SODIUM LAURYL SULFONATE 2386-53-0	N/L	N/L	N/L	N/L	N/L	N/L
PROGESTERONE 57-83-0	N/L	Listed as Schedule 4*	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
SODIUM LAURYL SULFONATE 2386-53-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L
PROGESTERONE 57-83-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

NOTES * Also listed as Schedule 5

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2024

SUPERSEDES

02/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

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.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.