



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 11

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name PROGESTERONE GEL 8%MIX

Other means of identification

Product Code 199791

Synonyms Prometrium, Endometrin, Crinone, Cyclogest

Recommended use of the chemical and restrictions on use

Recommended Use Prevention of Endometrial Hyperplasia in non-hysterectomized postmenopausal women who are receiving conjugated estrogen, Secondary Amenorrhea

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address

SDS@Allergan.com

Emergency telephone number

Emergency Telephone

Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

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

Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Germ cell mutagenicity	Category 2
Carcinogenicity	Category 1B
Reproductive toxicity	Category 2
Effects on or via lactation	Yes

Label elements

Emergency Overview

Danger

Hazard statements

H332 - Harmful if inhaled
H341 - Suspected of causing genetic defects
H350 - May cause cancer
H361 - Suspected of damaging fertility or the unborn child
H362 - May cause harm to breast-fed children



Appearance No information available

Physical state Solid

Odor No information available

Chemical Name
PROGESTERONE USP MICRONIZED

Symptoms

If this compound is inhaled, they may cause coughing and temporary bronchial irritation. Symptoms are generally alleviated upon breathing fresh air. Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact of this compound with the eyes may cause moderate to severe irritation, redness, and tearing. Common adverse effects from therapeutic use include cramps, abdominal pain, skeletal pain, perineal pain, headache, arthralgia, constipation, dyspareunia, nocturia, diarrhea, nausea, vomiting, breast enlargement, joint pain, flatulence, hot flushes, decreased libido, thirst, increased appetite, nervousness, drowsiness, excessive urination at night. Psychiatric effects including depression, mood swings, emotional instability, aggression, abnormal crying, insomnia, forgetfulness, sleep disorders. Less frequent adverse effects that may occur include allergy, anemia, bloating, fatigue, tremor, urticaria, pain, conjunctivitis, dizziness, vomiting, myalgia, back pain, breast pain, genital itching, genital yeast infection, upper respiratory tract infection, cystitis, dysuria, asthenia, xerophthalmia, syncope, dysmenorrhea, premenstrual tension, gastritis, urinary tract infection, vaginal discharge, pharyngitis, sweating, hyperventilation, vaginal dryness, dyspnea, fever, edema, flu-like symptoms, dry mouth, rhinitis, leg pain, skin discoloration, skin disorders, seborrhea, sinusitis, acne.

Chemical Name
PROGESTERONE USP MICRONIZED

Medical Conditions Aggravated by Exposure

Dermatitis and other skin disorders may be aggravated by exposure to this compound. In therapeutic use, conditions including thromboembolic and cardiovascular disorders or past history of these conditions, markedly impaired hepatic function, asthma, epilepsy, kidney disease, known or suspected carcinoma of breast or other estrogen-dependent neoplasia, pregnancy, and undiagnosed genital bleeding may be aggravated.

Precautionary statements

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P271 - Use only outdoors or in a well-ventilated area
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P312 - Call a POISON CENTER or doctor if you feel unwell
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P405 - Store locked up
- P501 - Dispose of contents/ container to an approved waste disposal plant
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P201 - Obtain special instructions before use
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash face, hands and any exposed skin thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Information

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
PURIFIED WATER USP	7732-18-5	231-791-2	60 - 100*
GLYCERINE USP (96%)	56-81-5	200-289-5	7 - 13*
PROGESTERONE USP MICRONIZED	57-83-0	200-350-6	5 - 10*
LIGHT MINERAL OIL NF	8042-47-5	232-455-8	1 - 5*
POLYCARBOPHIL USP	9003-97-8	N/A	1 - 5*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice	Immediate medical attention is required.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
Skin Contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Chemical Name
PROGESTERONE USP MICRONIZED

Note to physicians
Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact
Sensitivity to Static Discharge

Not impact sensitive.
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Use personal protective equipment as required. Keep people away from and upwind of spill/leak.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

Methods for containment Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)
GLYCERINE USP (96%) 56-81-5	N/A	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction (vacated) TWA: 10 mg/m ³ mist, total particulate (vacated) TWA: 5 mg/m ³ mist, respirable fraction	N/A	N/A

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Appearance	No information available
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property

pH	No information available
Melting point/freezing point	129 °C / 264 °F
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	1.166
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	3.87
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Values**Other Information**

Molecular weight	314.46
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY**Reactivity**

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
PURIFIED WATER USP	> 90 mL/kg (Rat)	N/A	N/A
GLYCERINE USP (96%)	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m ³ (Rat) 1 h

PROGESTERONE USP MICRONIZED	327 mg/kg (rat)	N/A	N/A
LIGHT MINERAL OIL NF	> 5000 mg/kg (Rat)	N/A	N/A
POLYCARBOPHIL USP	= 20 g/kg (Rat)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
GLYCERINE USP (96%)	Not mutagenic in the standard battery of tests.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	This product does not contain any known or suspected reproductive hazards.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.
PROGESTERONE USP MICRONIZED	No information available.	Suspected human carcinogen.	Suspected Reproductive Toxicant.	Detectable amounts of this compound have been identified in the milk of nursing women receiving this drug. Caution should be exercised when taking this compound is administered to nursing women.

Chronic toxicity

Prolonged or repeated exposure increases the risk. Possible risk of irreversible effects.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	3784 mg/kg
ATEmix (dermal)	77729 mg/kg
ATEmix (inhalation-dust/mist)	1.1 mg/l

12. ECOLOGICAL INFORMATION**Ecotoxicity**

11% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
GLYCERINE USP (96%) 56-81-5	N/A	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	500: 24 h Daphnia magna mg/L EC50
LIGHT MINERAL OIL NF 8042-47-5	N/A	10000: 96 h Lepomis macrochirus mg/L LC50	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
GLYCERINE USP (96%) 56-81-5	N/A	N/A	N/A	-1.76
PROGESTERONE USP MICRONIZED 57-83-0	N/A	N/A	Low mobility in soil	3.87
LIGHT MINERAL OIL NF 8042-47-5	N/A	N/A	N/A	>6

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS**Waste treatment methods****Disposal of wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging

Do not reuse container. Dispose of contents/containers in accordance with local

regulations.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Listed
EINECS/ELINCS	Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

Chemical Name	ACGIH	IARC	NTP	OSHA
PROGESTERONE USP MICRONIZED 57-83-0	-	Group 2B	Reasonably Anticipated	X

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive

Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals

Chemical Name	California Proposition 65
PROGESTERONE USP MICRONIZED - 57-83-0	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
GLYCERINE USP (96%) 56-81-5	X	X	X
PROGESTERONE USP MICRONIZED 57-83-0	X	X	X
SODIUM HYDROX 1.0N SOLN 1310-73-2	X	X	X

16. OTHER INFORMATION

Revision Date 02-Oct-2018
Revision Note No information available
Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet