



# SAFETY DATA SHEET

Revision date: 02-May-2015

Version: 3.0

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

### Product Identifier

**Material Name:** Medroxyprogesterone Acetate Injectable Suspension, USP - vials and pre-filled syringes  
(Greenstone LLC)

**Trade Name:** Not applicable  
**Synonyms:** Medroxyprogesterone Suspension, For Injection, IM  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as contraceptive agent

### Details of the Supplier of the Safety Data Sheet

Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1A  
Carcinogenicity: Category 2

#### EU Classification:

EU Indication of danger: Toxic to reproduction: Category 1  
Carcinogenic: Category 2

#### EU Risk Phrases:

R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H351 - Suspected of causing cancer  
H360FD - May damage fertility. May damage the unborn child.

**Precautionary Statements:** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.3;R40 Repr. Cat.1;R60-61	Carc. 2 (H351) Repr. 1A (H360FD)	15
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	Not Listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. If irritation occurs or persists, get medical attention.

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**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Medroxyprogesterone acetate

Manufacturer OEL: 2ug/m<sup>3</sup>, Skin

#### Sodium chloride

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### Polyethylene glycol

Austria OEL - MAKs 1000 mg/m<sup>3</sup>

Germany - TRGS 900 - TWAs 1000 mg/m<sup>3</sup>

Germany (DFG) - MAK 1000 mg/m<sup>3</sup> average molecular weight 200-600

Slovakia OEL - TWA 1000 mg/m<sup>3</sup>

Slovenia OEL - TWA 1000 mg/m<sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

##### Eyes:

Wear safety glasses or goggles if eye contact is possible.

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

##### Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Liquid suspension

#### Color:

White to off-white

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### Solubility:

Soluble: Water

#### pH:

No data available.

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Medroxyprogesterone acetate

No data available

#### Water for injection

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Polysorbate 80**

No data available

**Propylparaben**

No data available

**Methylparaben**

No data available

**Sodium chloride**

No data available

**Polyethylene glycol**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Short Term:** Not an eye irritant Not a skin irritant Not acutely toxic (based on animal data)

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs reproductive system the developing fetus. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

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### 11. TOXICOLOGICAL INFORMATION

**Known Clinical Effects:** Adverse effects associated with therapeutic use of medroxyprogesterone acetate include menstrual irregularities, abdominal pain or discomfort weight changes, dizziness, headache, weakness or fatigue, and nervousness. Clinical use of this drug has caused loss of libido impotence development of male characteristics in the female fetus

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Medroxyprogesterone acetate**

Rat Oral LD50 > 6,400 mg/kg  
Mouse Para-periosteal LD50 376mg/kg  
Rat Intraperitoneal LD50 > 400mg/kg  
Rat Subcutaneous LD50 > 8000mg/kg

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

##### **Propylparaben**

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

##### **Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD50 4000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Medroxyprogesterone acetate**

Eye Irritation Rabbit Non-irritating  
Skin Irritation Rabbit Mild

##### **Sodium chloride**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

##### **Polyethylene glycol**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **Medroxyprogesterone acetate**

10 Year(s) Monkey Intramuscular 3 mg/kg LOAEL Reproductive system  
18 Month(s) Mouse Intramuscular 200 mg/kg NOAEL None identified  
24 Month(s) Rat Intramuscular 200 mg/kg NOAEL None identified

##### **Propylparaben**

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

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### 11. TOXICOLOGICAL INFORMATION

4 Week(s) Rat Oral 347.2 mg/kg LOEL Male reproductive system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Medroxyprogesterone acetate**

Embryo / Fetal Development	Rat	Intramuscular	3 mg/kg	LOEL	Embryotoxicity, Not teratogenic
Embryo / Fetal Development	Monkey	Intramuscular	25 mg/kg	LOEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	Intramuscular	1 mg/kg	LOEL	Developmental toxicity
Embryo / Fetal Development	Rat	Subcutaneous	1 mg/kg	LOEL	Developmental toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Medroxyprogesterone acetate**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Micronucleus	Mouse	Negative
Chromosome Aberration	Rodent germ cell	Positive
Sister Chromatid Exchange	Rodent Lymphocytes	Positive

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Medroxyprogesterone acetate**

18 Month(s)	Mouse	Intramuscular	200 mg/kg/month	Not carcinogenic
24 Month(s)	Rat	Intramuscular	200 mg/kg/month	Not carcinogenic
18 Month(s)	Dog	Intramuscular	0.2 mg/kg	LOEL Benign tumors
40 Month(s)	Dog	Intramuscular	0.3 mg/kg	NOAEL Tumors, Mammary gland

**Carcinogen Status:** See below

##### **Medroxyprogesterone acetate**

**IARC:** Group 2B (Possibly Carcinogenic to Humans)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

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### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision A



**Medroxyprogesterone acetate**

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed  
carcinogen initial date 1/1/90  
developmental toxicity initial date 4/1/90

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

200-757-9

**Water for injection**

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

REACH - Annex IV - Exemptions from the  
obligations of Register:

Present

EU EINECS/ELINCS List

231-791-2



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### 15. REGULATORY INFORMATION

#### Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

#### Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

#### Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.  
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer

Carcinogenic: Category 3  
Toxic to reproduction: Category 1

R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

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**Reasons for Revision:**

Updated Section 2 - Hazard Identification. Updated Section 15 - Regulatory Information.  
Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling  
and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1  
- Identification of the Substance/Preparation and the Company/Undertaking. Updated Section  
16 - Other Information.

**Revision date:**

02-May-2015

Product Stewardship Hazard Communication

**Prepared by:**

Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

**End of Safety Data Sheet**