

SAFETY DATA SHEETS

This SDS packet was issued with item:

078380880

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078938422



MATERIAL SAFETY DATA SHEET

Revision date: 02-May-2011

Version: 2.4

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

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

Emergency telephone number:
800-435-7095

Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

Material Name: Medroxyprogesterone Acetate Injectable Suspension, USP - vials and pre-filled syringes

Trade Name:	Not applicable
Synonyms:	None
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as, contraceptive agent

2. HAZARDS IDENTIFICATION

Appearance: White to off-white suspension
Signal Word: DANGER

Statement of Hazard: May damage fertility or the unborn child.
Suspected of causing cancer.

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.

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

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.
R60 - May impair fertility.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.3;R40 Repr. Cat.1;R60-61	15
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
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.
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.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

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

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

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

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Medroxyprogesterone acetate

Manufacturer OEL: 2ug/m³, Skin

Polyethylene glycol

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ MAK
Slovenia OEL - TWA	Listed

Sodium chloride

Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

Analytical Method: An analytical method may be available for the compound(s) listed above (Contact Greenstone for additional details)

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, disposable gloves (double suggested) 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 disposable 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Suspension	Color:	White to off-white
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Water solubility:	Freely soluble		
pH:	3.0 - 7.0		
Flash Point (Liquid) (°C):		Non-flammable	
Polymerization:		Will not occur	

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

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

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

Polysorbate 80

Rat Oral LD50 25 g/kg

Methylparaben

Mouse Oral LD50 > 8000 mg/kg

Rat Oral LD50 2280 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg

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

Medroxyprogesterone acetate

Rat Oral LD50 > 6,400 mg/kg

Mouse Para-periosteal LD50 376 mg/kg

Rat Intraperitoneal LD50 > 400 mg/kg

Rat Subcutaneous LD50 > 8000 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)

Polyethylene glycol

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11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Medroxyprogesterone acetate

Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

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

Medroxyprogesterone acetate

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

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

Medroxyprogesterone acetate

Bacterial Mutagenicity (Ames) *Salmonella* 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

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12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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

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

EU Risk Phrases:
R45 - May cause cancer.
R60 - May impair fertility.

EU Safety Phrases:
S22 - Do not breathe dust.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May damage fertility or the unborn child.
Suspected of causing cancer.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

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15. REGULATORY INFORMATION



Medroxyprogesterone acetate

California Proposition 65

carcinogen, initial date 1/1/90
developmental toxicity, initial date 4/1/90

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

200-757-9

Polyethylene glycol

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

Listed

Australia (AICS):

Listed

Polysorbate 80

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

Listed

Australia (AICS):

Listed

Sodium chloride

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

231-598-3

Methylparaben

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

202-785-7

Propylparaben

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

202-307-7

Water for injection

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

Listed

Australia (AICS):

Listed

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

Present

EU EINECS/ELINCS List

231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R40 - Limited evidence of a carcinogenic effect

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

Data Sources:

The data contained in this MSDS 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 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by:

Product Stewardship Hazard Communications
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