SAFETY DATA SHEET

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

Product Identifier

Material Name: Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg/ml

Trade Name: DEPO-PROVERA; DEPO-PRODASONE; FARLUTAL; FARLUTAL DEPO; ONCO-PROVERA; DEPO-RALOVERA; SAYANA; DEPOCON

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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

Other Hazards
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 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

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

<table>
<thead>
<tr>
<th>Additional Information:</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Proprietary</td>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>*</td>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
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</tr>
<tr>
<td>*</td>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>*</td>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
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<td>Not Listed</td>
<td>*</td>
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</table>

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.

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 Aggravated by Exposure: None known

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
7. HANDLING AND STORAGE  
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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Medroxyprogesterone acetate
Pfizer OEL TWA-8 Hr: 2 µg/m³, Skin

Sodium chloride
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL -TWAs 1000 ppm

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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
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<tr>
<td>Water Solubility:</td>
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<tr>
<td>Color:</td>
<td>White to off-white</td>
</tr>
<tr>
<td>Odor Threshold:</td>
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</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg/ml
Revision date: 11-Aug-2014

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility: Soluble</td>
<td>Water</td>
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<tr>
<td>pH:</td>
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<tr>
<td>Melting/Freezing Point (°C):</td>
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<tr>
<td>Boiling Point (°C):</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Decomposition Temperature (°C):</td>
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<tr>
<td>Evaporation Rate (Gram/s):</td>
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<tr>
<td>Vapor Pressure (kPa):</td>
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<tr>
<td>Vapor Density (g/ml):</td>
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</tr>
<tr>
<td>Relative Density:</td>
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<tr>
<td>Viscosity:</td>
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</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
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</tr>
<tr>
<td>Flammability (Solids):</td>
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<tr>
<td>Flash Point (Liquid) (°C):</td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
</tbody>
</table>

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).

PZ01162
11. TOXICOLOGICAL INFORMATION

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).

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 Intramuscular3 mg/kg LOAEL Reproductive system
11. TOXICOLOGICAL INFORMATION

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 (Possibly Carcinogenic to Humans)
- OSHA: Listed

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
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: Not Listed
- California Proposition 65: 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

Methylparaben
- 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: 202-785-7
15. REGULATORY INFORMATION

Water for injection
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register:
- EU EINECS/ELINCS List: 231-791-2

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

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

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: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

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: 11-Aug-2014
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without 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