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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Medroxyprogesterone Acetate Injectable Suspension, 400 mg/ml

Trade Name: DEPO-PROVERA® Sterile Aqueous Suspension
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for menstrual irregularities

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid
Signal Word: DANGER

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

Additional Hazard 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

EU Classification
EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 3

EU Hazard Symbols:

EU Risk Phrases:
2. HAZARDS IDENTIFICATION

R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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 Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU 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>40</td>
</tr>
<tr>
<td>Sodium sulfate anhydrous</td>
<td>7757-82-6</td>
<td>231-820-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>2748-88-1</td>
<td>220-387-1</td>
<td>Xn;R22</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.

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: Minimize generating airborne mists and vapors. 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. 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
   Pfizer OEL TWA-8 Hr: 2 µg/m³, Skin

Sodium sulfate anhydrous
   Latvia OEL - TWA: 10 mg/m³
   Lithuania OEL - TWA: 10 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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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
Molecular Formula: Mixture
Color: Clear
Molecular Weight: Mixture
Solubility: Soluble: Water

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 active ingredient(s).

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

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

Myristyl-gamma-picolinium chloride
Rat Oral LD50 250 mg/kg
Rat Para-periosteal LD50 30 mg/kg
Rat Intraperitoneal LD50 7500 ug/kg
Rat Subcutaneous LD50 200 mg/kg
## 11. TOXICOLOGICAL INFORMATION

### Sodium sulfate anhydrous

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>LOAEL</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>5989 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>IV</td>
<td>1220 mg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

### Medroxyprogesterone acetate

#### Eye Irritation
- Rabbit: Non-irrating

#### Skin Irritation
- Rabbit: Mild

#### Polyethylene glycol
- Rabbit: Mild

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

#### Medroxyprogesterone acetate

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Year(s)</td>
<td>Monkey</td>
<td>Intramuscular</td>
<td>3 mg/kg</td>
<td>LOAEL</td>
<td>Reproductive system</td>
</tr>
<tr>
<td>18 Month(s)</td>
<td>Mouse</td>
<td>Intramuscular</td>
<td>200 mg/kg</td>
<td>NOAEL</td>
<td>None identified</td>
</tr>
<tr>
<td>24 Month(s)</td>
<td>Rat</td>
<td>Intramuscular</td>
<td>200 mg/kg</td>
<td>NOAEL</td>
<td>None identified</td>
</tr>
</tbody>
</table>

#### Myristyl-gamma-picolinium chloride

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 Day(s)</td>
<td>Dog</td>
<td>Intramuscular</td>
<td>0.2 mg/kg</td>
<td>LOEL: Benign tumors</td>
</tr>
</tbody>
</table>

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

#### Medroxyprogesterone acetate

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Intramuscular</td>
<td>3 mg/kg</td>
<td>LOAEL: Embryotoxicity, Not teratogenic</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Monkey</td>
<td>Intramuscular</td>
<td>25 mg/kg</td>
<td>LOAEL: Developmental toxicity</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>1 mg/kg</td>
<td>LOAEL: Developmental toxicity</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>1 mg/kg</td>
<td>LOAEL: Developmental toxicity</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Month(s)</td>
<td>Mouse</td>
<td>Intramuscular</td>
<td>200 mg/kg/month</td>
<td>Not carcinogenic</td>
<td></td>
</tr>
<tr>
<td>24 Month(s)</td>
<td>Rat</td>
<td>Intramuscular</td>
<td>200 mg/kg/month</td>
<td>Not carcinogenic</td>
<td></td>
</tr>
<tr>
<td>18 Month(s)</td>
<td>Dog</td>
<td>Intramuscular</td>
<td>0.2 mg/kg</td>
<td>LOEL: Benign tumors</td>
<td></td>
</tr>
<tr>
<td>40 Month(s)</td>
<td>Dog</td>
<td>Intramuscular</td>
<td>0.3 mg/kg</td>
<td>NOAEL: Tumors, Mammary gland</td>
<td></td>
</tr>
</tbody>
</table>

### Carcinogen Status:

- See below
11. TOXICOLOGICAL INFORMATION

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.

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 3

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

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)
Australia (AICS):
Present
EU EINECS/ELINCS List
200-757-9

Water
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Present
REACH - Annex IV - Exemptions from the
obligations of Register:
EU EINECS/ELINCS List
231-791-2

Sodium sulfate anhydrous
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Present
EU EINECS/ELINCS List
231-820-9

Polyethylene glycol
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Present
Standard for the Uniform Scheduling
for Drugs and Poisons:
Schedule 3

Myristyl-gamma-picolinium chloride
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Present
EU EINECS/ELINCS List
220-387-1

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect
MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable Suspension, 400 mg/ml
Revision date: 09-Apr-2013

Data Sources:
Pfizer proprietary drug development information.

Reasons for Revision:
Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures.

Prepared by:
Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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