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

Product Identifier
- Material Name: Medroxyprogesterone Acetate Injectable Suspension, 400 mg/ml
- Trade Name: DEPO-PROVERA® Sterile Aqueous Suspension
- Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
- Intended Use: Pharmaceutical product used for menstrual irregularities

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

- 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
- Contact E-Mail: pfizer-MSDS@pfizer.com

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 3

- EU Risk Phrases:
  - R40 - Limited evidence of a carcinogenic effect.
  - 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:
  - P202 - Do not handle until all safety precautions have been read and understood
  - P281 - Use personal protective equipment as required
  - 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):
No data available

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>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</td>
<td>Carc. 2 (H351)</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.1;R60-61</td>
<td>Repr. 1A (H360FD)</td>
<td></td>
</tr>
<tr>
<td>Sodium sulfate anhydrous</td>
<td>7757-82-6</td>
<td>231-820-9</td>
<td>Not Listed</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>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>Acute Tox.3 (H301)</td>
<td>&lt;1.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<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>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</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.
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 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.
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: Formation of toxic gases is possible during heating or fire.

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
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.

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.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Exposure Limits</th>
<th>Source/Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone acetate</td>
<td>2 µg/m³, Skin</td>
<td>Pfizer OEL TWA-8 Hr</td>
</tr>
<tr>
<td>Sodium sulfate anhydrous</td>
<td>10 mg/m³</td>
<td>Latvia OEL - TWA</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>Lithuania OEL - TWA</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>1000 mg/m³</td>
<td>Austria OEL - MAK</td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
<td>Germany - TRGS 900 - TWAs</td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
<td>Germany (DFG) - MAK</td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
<td>Slovakia OEL - TWA</td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
<td>Slovenia OEL - TWA</td>
</tr>
<tr>
<td></td>
<td>1000 ppm</td>
<td>Switzerland OEL - TWAs</td>
</tr>
</tbody>
</table>

**Analytical Method:**
Analytical method available for Medroxyprogesterone. Contact Pfizer Inc for further information.

**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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value) Medroxyprogesterone acetate</td>
<td>No data available</td>
</tr>
<tr>
<td>Water</td>
<td>No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Myristyl-gamma-picolinium chloride
Predicted PZ01149

Polyethylene glycol
No data available

Sodium sulfate anhydrous
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 active ingredient(s).

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)
11. TOXICOLOGICAL INFORMATION

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

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

Sodium sulfate anhydrous
- Mouse Oral LD50 5989 mg/kg
- Rabbit IV LD50 1220mg/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

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

Myristyl-gamma-picolinium chloride
- 60 Day(s) Rat Oral 2400 mg/kg Death

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
11. TOXICOLOGICAL INFORMATION

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:
Partition Coefficient: (Method, pH, Endpoint, Value)
Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30

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

**Sodium sulfate anhydrous**

- **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:** 231-820-9

**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

**Water**

- **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:** Present
15. REGULATORY INFORMATION

| EU EINECS/ELINCS List | 231-791-2 |

Myristyl-gamma-picolinium 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: 220-387-1

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
Acute toxicity, oral - Cat. 3; H301 - Toxic if swallowed

Carcinogenic: Category 3
Toxic to reproduction: Category 1
Xn - Harmful

R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect

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 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 18-Mar-2015

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