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

Material Name: Medroxyprogesterone Acetate Suspension - Uniject

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>DEPO-PROVERA; SAYANA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Medroxyprogesterone Suspension for Injection, Subcutaneous</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as contraceptive agent</td>
</tr>
</tbody>
</table>

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.

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:

T
2. HAZARDS IDENTIFICATION

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

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>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</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.1;R60-61</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methionine</td>
<td>63-68-3</td>
<td>200-562-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyoethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C;R35</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C;R35 T;R23</td>
<td>**</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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium Phosphate Monobasic, Monohydrate</td>
<td>10049-21-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Disodium phosphate dodecahydrate</td>
<td>10039-32-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH

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 eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Suspension - Uniject
Revision date: 09-Apr-2013
Version: 4.0

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.

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: Carbon dioxide, carbon monoxide

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: 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.

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
Pfizer OEL TWA-8 Hr: 2 µg/m³, Skin

PZ01739
**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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

**Methionine**
- Latvia 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

**Sodium hydroxide**
- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Bulgaria OEL - TWA: 2.0 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
- France OEL - TWA: 2 mg/m³
- Greece OEL - TWA: 2 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Japan - OELs - Ceilings: 2 mg/m³
- Latvia OEL - TWA: 0.5 mg/m³
- OSHA - Final PELS - TWAs: 2 mg/m³
- Poland OEL - TWA: 0.5 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
- Sweden OEL - TWAs: 1 mg/m³

**Hydrochloric Acid**
- ACGIH Ceiling Threshold Limit: 2 ppm
- Australia PEAK: 5 ppm
- Bulgaria OEL - TWA: 5 ppm
- Belgium OEL - TWA: 8 mg/m³
- Cyprus OEL - TWA: 5 ppm
- Czech Republic OEL - TWA: 8 mg/m³
- Estonia OEL - TWA: 8 mg/m³
- Germany - TRGS 900 - TWAs: 2 ppm
- Germany (DFG) - MAK: 2 ppm
- 3 mg/m³
- Germany (DFG) - MAK: 3.0 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece</td>
<td>5 ppm</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan</td>
<td>5 ppm</td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Latvia</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovenia</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>5 ppm</td>
<td>7.6 mg/m³</td>
</tr>
</tbody>
</table>


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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid suspension</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>White to off-white</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

**Methylparaben**
Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

**Sodium chloride**
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

**Povidone**
Rat Oral LD50 100 g/kg

**Sodium hydroxide**
Mouse IP LD50 40 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

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)

**Sodium chloride**
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

**Polyethylene glycol**
11. TOXICOLOGICAL INFORMATION

Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Hydrochloric Acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

Medroxyprogesterone acetate
Eye Irritation  Rabbit  Non-irritating
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
11. TOXICOLOGICAL INFORMATION

Povidone
IARC: Group 3 (Not Classifiable)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

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

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

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

Medroxyprogesterone acetate
  California Proposition 65  carcinogen initial date 1/1/90
devitational 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
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS/ELINCS List  202-785-7

Sodium chloride
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS/ELINCS List  231-598-3

Water for injection
  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

Polysorbate 80
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present

Povidone
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present

Methionine
  Inventory - United States TSCA - Sect. 8(b)  Present
15. REGULATORY INFORMATION

Australia (AICS): Present
EU EINECS/ELINCS List 200-562-9

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

Sodium hydroxide
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5 Schedule 6
EU EINECS/ELINCS List 215-185-5

Sodium Phosphate Monobasic, Monohydrate
Australia (AICS): Present

Propylparaben
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-307-7

Disodium phosphate dodecahydrate
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb 2270 kg
Australia (AICS): Present

Hydrochloric Acid
CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs 500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances 5000 lb
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5 Schedule 6
EU EINECS/ELINCS List 231-595-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R23 - Toxic by inhalation.
R35 - Causes severe burns.
R40 - Limited evidence of a carcinogenic effect
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 15 - Regulatory Information.
- Updated Section 2 - Hazard Identification.
- Updated Section 3 - Composition / Information on Ingredients.
- Updated Section 7 - Handling and Storage.
- Updated Section 12 - Ecological Information.

**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