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

Product Identifier

Material Name: Medroxyprogesterone Acetate Suspension - Uniject

Trade Name: DEPO-PROVERA; SAYANA
Synonyms: Medroxyprogesterone Suspension for Injection, Subcutaneous; DEPO-SUBQ PROVERA; depo-subQ provera 104
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

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

Label Elements

Signal Word: Danger
Hazard Statements:
H351 - Suspected of causing cancer
H360FD - May damage fertility. May damage the unborn child.
SAFETY DATA SHEET

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

<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 Repr. Cat.1;R60-61</td>
<td>Carc. 2 (H351) Repr. 1A (H360FD)</td>
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<tr>
<td>Methionine</td>
<td>63-68-3</td>
<td>200-562-9</td>
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<td>Not Listed</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A (H314)</td>
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<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23 C; R35</td>
<td>Press. Gas Skin Corr. 1A; H314 Acute Tox. 3; H331</td>
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<td>Sodium chloride</td>
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<tr>
<td>Polyethylene glycol</td>
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<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>
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</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
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<td>Povidone</td>
<td>9003-39-8</td>
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<tr>
<td>Sodium Phosphate Monobasic, Monohydrate</td>
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<td>Polysorbate 80</td>
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</table>

Additional Information:
- * Proprietary
- ** to adjust pH

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.
SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Suspension - Uniject
Revision date: 18-Mar-2015

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
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

Methionine
Latvia OEL - TWA 5 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
Switzerland OEL - TWAs 2 mg/m³

Hydrochloric Acid
ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
Austria OEL - MAKs 5 ppm
Belgium OEL - TWA 5 ppm
Bulgaria OEL - TWA 5 ppm

PZ01739
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL/TWA</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
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</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
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<td>7 mg/m³</td>
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<tr>
<td>Hungary OEL - TWA</td>
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<tr>
<td>Ireland OEL - TWAs</td>
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<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>5 ppm</td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
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<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
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<tr>
<td>Malta OEL - TWA</td>
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</tr>
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<td>Netherlands OEL - TWA</td>
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<td>Portugal OEL - TWA</td>
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<td>8 mg/m³</td>
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<tr>
<td>Romania OEL - TWA</td>
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<td>8.0 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
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<td>7.6 mg/m³</td>
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<td>Vietnam OEL - TWAs</td>
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<tr>
<td>Sodium chloride</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol</td>
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<td>Austria OEL - MAKs</td>
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<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ average molecular weight 200-600</td>
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<tr>
<td>Slovakia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>1000 ppm</td>
<td></td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


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

Physical State: Liquid suspension
Odor: No data available.
Molecular Formula: Mixture
Color: White to off-white
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value) No data available

Water for injection
No data available
Polysorbate 80
No data available
Propylparaben
No data available
Methylparaben
No data available
Sodium chloride
No data available
Polyethylene glycol
No data available
Sodium Phosphate Monobasic, Monohydrate
No data available
Disodium phosphate dodecahydrate
No data available
Povidone
No data available
Hydrochloric Acid
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Sodium hydroxide
No data available

Methionine
No data available

Medroxyprogesterone acetate
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 individual ingredients.

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 show 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)

Polysorbate 80
11. TOXICOLOGICAL INFORMATION

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

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-periosteaal  LD50  376mg/kg
Rat  Intraperitoneal  LD50  > 400mg/kg
Rat  Subcutaneous  LD50  > 8000mg/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
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Hydrochloric Acid
Skin Irritation  Severe
Eye Irritation  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)
11. TOXICOLOGICAL INFORMATION

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

Povidone
IARC: Group 3 (Not Classifiable)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

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: 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
Inventory - United States TSCA - Sect. 8(b)
Carcinogen initial date 1/1/90
developmental toxicity initial date 4/1/90
Present
## 15. REGULATORY INFORMATION

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<th>Material Name: Sodium hydroxide</th>
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<td>California Proposition 65 Not Listed</td>
</tr>
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<td>Methylparaben</td>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
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<tr>
<td>California Proposition 65 Not Listed</td>
<td>Australia (AICS): Present</td>
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<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td>EU EINECS/ELINCS List 202-785-7</td>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>Water for injection</td>
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<td>California Proposition 65 Not Listed</td>
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<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
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<tr>
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<td>Australia (AICS): Present</td>
<td>EU EINECS/ELINCS List Not Listed</td>
</tr>
<tr>
<td>Povidone</td>
<td>Methionine</td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
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<td>EU EINECS/ELINCS List 200-562-9</td>
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</tr>
<tr>
<td>Methionine</td>
<td>Sodium hydroxide</td>
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<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
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<tr>
<td>California Proposition 65 Not Listed</td>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
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<tr>
<td>Australia (AICS): Present</td>
<td>California Proposition 65 Not Listed</td>
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15. REGULATORY INFORMATION

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SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Suspension - Unject
Revision date: 18-Mar-2015

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
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.3; H331 - Toxic if inhaled

C - Corrosive
Carcinogenic: Category 3
Toxic to reproduction: Category 1
T - Toxic

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 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 18-Mar-2015
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