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

Material Name: Medroxyprogesterone Acetate Subcutaneous Injection, 104 mg/0.65 mL
Trade Name: DEPO-SUBQ PROVERA 104
Synonyms: DMPA-SC
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as contraceptive agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone acetate</td>
<td>71-58-9</td>
<td>200-757-9</td>
<td>15</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>**</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>**</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methionine</td>
<td>63-68-3</td>
<td>200-562-9</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>7556-79-4</td>
<td>231-448-7</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium phosphate, monobasic</td>
<td>7558-80-7</td>
<td>231-449-2</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</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.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white suspension
Signal Word: DANGER

Statement of Hazard:
Possible carcinogen
May cause harm to the unborn child.
May cause reproductive system effects
Additional Hazard Information:

Short Term: Not expected to cause eye irritation. (based on components). Active ingredient is not a skin irritant. Not acutely toxic (based on animal data). May be absorbed through the skin and cause systemic effects.

Long Term: The use of oral contraceptives is associated with increased risk of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease.

Known Clinical Effects: Adverse effects associated with the therapeutic use of medroxyprogesterone acetate include menstrual irregularities, abdominal pain or discomfort, weight changes, dizziness, headache, weakness or fatigue, and nervousness.

EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 2

EU Hazard Symbols:

EU Risk Phrases:

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards: Not applicable

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:** Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing.

**Storage Conditions:** Store in a cool, dry, well-ventilated area.

**Storage Temperature:** 20-25°C (68-77°F)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Medroxyprogesterone acetate**

- Pfizer OEL TWA-8 Hr: 2 ug/m³ Skin

**Hydrogen chloride**

- ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
- Australia PEAK: = 5 ppm Peak
- = 7.5 mg/m³ Peak

**Sodium hydroxide**

- OSHA - Final PELS - TWAs: 2 mg/m³
- ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
- Australia PEAK: = 2 mg/m³ Peak

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

- **Hands:** Rubber gloves
- **Eyes:** Safety glasses or goggles
- **Skin:** Wear protective clothing when working with large quantities.
- **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:** Suspension

**Molecular Formula:** Mixture

**Color:** White to off-white

**Molecular Weight:** Mixture

**Solubility:** Highly soluble: Water
10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: None known
Hazardous Decomposition Products: None known
Polymerization: Will not occur

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)

Medroxyprogesterone acetate
- Rat Oral LD50 > 6,400 mg/kg
- Mouse Intravenous LD50 376 mg/kg
- Rat Intraperitoneal LD50 > 400 mg/kg
- Rat Subcutaneous LD50 > 8000 mg/kg

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

Povidone
- Rat Oral LD50 100 g/kg

Propylparaben
- Mouse Oral LD50 6332 mg/kg
- Mouse Intraperitoneal LD50 200 mg/kg

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

Polysorbate 80
- Rat Oral LD50 25 g/kg

Sodium hydroxide
- Mouse IP LD50 40 mg/kg

Hydrogen chloride
- Rat Inhalation LC50 1H 3,124 ppm
- Mouse Inhalation LC50 1H 1,108 ppm
- Mouse Oral LD50 900 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)
MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Subcutaneous Injection, 104 mg/0.65 mL
Revision date: 02-Jan-2007

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

**Medroxyprogesterone acetate**
- Eye Irritation: Rabbit, Non-irritating
- Skin Irritation: Rabbit, Mild

**Sodium phosphate, dibasic**
- Eye Irritation: Rabbit, Mild
- Skin Irritation: Rabbit, Mild

**Sodium chloride**
- Eye Irritation: Rabbit, Moderate
- Skin Irritation: Rabbit, Mild

**Polyethylene glycol**
- Eye Irritation: Rabbit, Mild
- Skin Irritation: Rabbit, Mild

**Sodium hydroxide**
- Eye Irritation: Rabbit, Severe
- Skin Irritation: Rabbit, Severe

**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

**Sodium chloride**
- 10 Day(s): Rat, Oral, 12500 mg/kg, LOAEL, Kidney, Ureter, Bladder

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
  OSHA: Present

Povidone
  IARC: Group 3

Hydrogen chloride
  IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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 2

EU Risk Phrases:
  R45 - May cause cancer.
  R60 - May impair fertility.
  R61 - May cause harm to the unborn child.

EU Safety Phrases:
  S22 - Do not breathe dust.
  S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
  S53 - Avoid exposure - obtain special instructions before use.
OSHA Label:
DANGER
Possible carcinogen
May cause harm to the unborn child.
May cause reproductive system effects

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

Methionine

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-562-9

Povidone

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

Hydrogen chloride

CERCLA/SARA 313 Emission reporting = 1.0 % de minimis concentration
acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size

CERCLA/SARA Hazardous Substances and their Reportable Quantities:
= 2270 kg final RQ
= 5000 lb final RQ
= 500 lb TPQ gas only

CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs
= 5000 lb EPCRA RQ gas only

Inventory - United States TSCA - Sect. 8(b) T
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
Schedule 6
EU EINECS List 231-595-7

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:
= 1000 lb final RQ
= 454 kg final RQ

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety
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End of Safety Data Sheet