



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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**1-212-573-2222**

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**+00 44 (0)1304 616161**

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**

**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

**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

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

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

### 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

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### 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

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**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/m<sup>3</sup>Skin

**Hydrogen chloride**  
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling  
Australia PEAK = 5 ppm Peak  
= 7.5 mg/m<sup>3</sup> Peak

**Sodium hydroxide**  
OSHA - Final PELs - TWAs: 2 mg/m<sup>3</sup>  
ACGIH Ceiling Threshold Limit: = 2 mg/m<sup>3</sup> Ceiling  
Australia PEAK = 2 mg/m<sup>3</sup> 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

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pH: 5.7 - 7.0  
Specific Gravity: 1.044

### 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 LD 50 6332 mg/kg  
Mouse Intraperitoneal LD 50 200 mg/kg

##### **Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD 50 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)

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### 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

### 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

#### 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

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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.

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## 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

CERCLA/SARA - Section 302 Extremely Hazardous  
TPQs

= 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

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Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5
<b>Sodium phosphate, dibasic</b>	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-448-7
<b>Polysorbate 80</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Sodium phosphate, monobasic</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-449-2
<b>Sodium chloride</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-598-3
<b>Methylparaben</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7
<b>Water for injection</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
<b>Polyethylene glycol</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Propylparaben</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

## 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**