



MATERIAL SAFETY DATA SHEET

Revision date: 14-Feb-2008

Version: 1.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Medroxyprogesterone Acetate Oral Suspension

Trade Name: FARLUTAL; PROVERA
Chemical Family: Mixture
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

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

Statement of Hazard: May cause cancer.
May damage fertility or the unborn child.

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 the 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, and development of male characteristics in the female fetus.

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.

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Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|-----------------------------|------------|-----------------------|---------------------------------------|----|
| Medroxyprogesterone acetate | 71-58-9 | 200-757-9 | Carc. Cat.2;R45 Repr. Cat.1;R60-61 | 10 |
| Glycerol | 56-81-5 | 200-289-5 | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|-------------------------|------------|-----------------------|----------------|---|
| Citric acid monohydrate | 5949-29-1 | Not listed | Not Listed | * |
| Peppermint oil | 8006-90-4 | Not listed | Not Listed | * |
| Methylparaben | 99-76-3 | 202-785-7 | Not Listed | * |
| Croscarmellose sodium | 74811-65-7 | Not listed | Not Listed | * |
| Sodium citrate | 68-04-2 | 200-675-3 | Not Listed | * |
| Polysorbate 80 | 9005-65-6 | Not listed | Not Listed | * |
| Propylparaben | 94-13-3 | 202-307-7 | Not Listed | * |
| Water, purified | 7732-18-5 | 231-791-2 | Not Listed | * |
| Sorbitol | 6706-59-8 | Not listed | Not Listed | * |

Additional Information:

* Proprietary
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.
- 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.

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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 thoroughly after handling. |
| 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/m³Skin

Glycerol

| | |
|-----------------------------------|----------------------------------|
| ACGIH Threshold Limit Value (TWA) | = 10 mg/m ³ TWA |
| Australia TWA | = 10 mg/m ³ TWA |
| Belgium OEL - TWA | = 10 mg/m ³ TWA |
| Estonia OEL - TWA | = 10 mg/m ³ TWA |
| Finland OEL - TWA | = 20 mg/m ³ TWA |
| France OEL - TWA | = 10 mg/m ³ VME |
| Greece OEL - TWA | = 10 mg/m ³ TWA |
| Ireland OEL - TWAs | = 10 mg/m ³ TWA |
| Netherlands OEL - TWA | = 10 mg/m ³ MAC |
| OSHA - Final PELs - TWAs: | = 15 mg/m ³ TWA total |
| | = 5 mg/m ³ TWA |
| Poland OEL - TWA | = 10 mg/m ³ NDS |
| Portugal OEL - TWA | = 10 mg/m ³ TWA |
| Spain OEL - TWA | = 10 mg/m ³ VLA-ED |

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

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:

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 | Color: | White to off-white |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solubility: | Soluble: Water | | |

10. STABILITY AND REACTIVITY

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 Intraperitoneal LD 50 200 mg/kg

Methylparaben

Mouse Oral LD50 > 8000 mg/kg

Rat Oral LD50 2280 mg/kg

Medroxyprogesterone acetate

Rat Oral LD50 > 6,400 mg/kg

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| | | | |
|-------|-----------------|------|--------------|
| Mouse | Intravenous | LD50 | 376 mg/kg |
| Rat | Intraperitoneal | LD50 | > 400 mg/kg |
| Rat | Subcutaneous | LD50 | > 8000 mg/kg |

Peppermint oil

| | | | |
|-------|------|-------|------------|
| Rat | Oral | LD 50 | 2426 mg/kg |
| Mouse | Oral | LD 50 | 2490 mg/kg |

Glycerol

| | | | |
|-----|------|-------|-------------|
| Rat | Oral | LD 50 | 12600 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)

Medroxyprogesterone acetate

| | | |
|-----------------|--------|----------------|
| Eye Irritation | Rabbit | Non-irritating |
| Skin Irritation | Rabbit | Mild |

Citric acid monohydrate

| | | |
|-----------------|--------|------|
| Eye Irritation | Rabbit | Mild |
| Skin Irritation | Rabbit | Mild |

Glycerol

| | | |
|-----------------|--------|------|
| Skin Irritation | Rabbit | Mild |
| Eye 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 |

Glycerol

| | | | | | |
|-----------|-----|------|-------------|-------|------------------|
| 28 Day(s) | Rat | Oral | 16800 mg/kg | LOAEL | Endocrine system |
|-----------|-----|------|-------------|-------|------------------|

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 |

Glycerol

| | | | | | |
|--------------------------------|-----|------|-----------|------|-----------|
| Reproductive & Fertility-Males | Rat | Oral | 100 mg/kg | LOEL | Fertility |
|--------------------------------|-----|------|-----------|------|-----------|

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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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 (Possibly Carcinogenic to Humans)
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

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:

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

EU Safety Phrases:

S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER

May cause cancer.

May damage fertility or the unborn child.

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/ELINCS List

200-757-9

Citric acid monohydrate

Australia (AICS):

Present

Glycerol

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

200-289-5

Peppermint oil

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

Methylparaben

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

202-785-7

Croscarmellose sodium

Australia (AICS):

Present

Sodium citrate

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| | |
|---|------------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | Schedule 6 |
| | 200-675-3 |
| Polysorbate 80 | |
| Inventory - United States TSCA - Sect. 8(b) | XU |
| Australia (AICS): | Present |
| Propylparaben | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 202-307-7 |
| Water, purified | |
| 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 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R45 - May cause cancer.

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.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet