



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Mar-2012

Version: 2.0

Page 1 of 9

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

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### 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 damage fertility or the unborn child.  
Suspected of causing cancer.  
Toxic to aquatic life with long lasting effects.

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, and development of male characteristics in the female fetus.

EU Classification

EU Indication of danger: Toxic to reproduction: Category 1  
Carcinogenic: Category 3  
Dangerous for the Environment

EU Hazard Symbols:



EU Risk Phrases:

# MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 2 of 9

Version: 2.0

## 2. HAZARDS IDENTIFICATION

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R40 - Limited evidence of a carcinogenic effect  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### 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	EU Classification	%
Glycerol	56-81-5	200-289-5	Not Listed	*
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.3;R40 Repr. Cat.1;R60-61,R50/53	10

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

## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 3 of 9

Version: 2.0

**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 thoroughly after handling. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

**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.

#### Glycerol

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	20 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>

## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 4 of 9

Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	50 mg/m <sup>3</sup> inhalable fraction
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

Medroxyprogesterone acetate  
Pfizer OEL TWA-8 Hr: 2 µg/m<sup>3</sup>, Skin

<b>Analytical Method:</b>	Analytical method available for Medroxyprogesterone. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Liquid suspension	<b>Color:</b>	White to off-white
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water		

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	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)**

## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 5 of 9

Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### Polysorbate 80

Rat Oral LD50 25 g/kg

#### Propylparaben

Mouse Oral LD50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD50 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  
Mouse Para-periosteal LD50 376 mg/kg  
Rat Intraperitoneal LD50 > 400 mg/kg  
Rat Subcutaneous LD50 > 8000 mg/kg

#### Peppermint oil

Rat Oral LD50 2426 mg/kg  
Mouse Oral LD50 2490 mg/kg

#### Glycerol

Rat Oral LD50 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

## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 6 of 9

Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### Glycerol

28 Day(s) Rat Oral 16800 mg/kg LOEL Endocrine system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Medroxyprogesterone acetate

Embryo / Fetal Development Rat Intramuscular 3 mg/kg LOEL Embryotoxicity, Not teratogenic  
Embryo / Fetal Development Monkey Intramuscular 25 mg/kg LOEL Developmental toxicity  
Embryo / Fetal Development Rabbit Intramuscular 1 mg/kg LOEL Developmental toxicity  
Embryo / Fetal Development Rat Subcutaneous 1 mg/kg LOEL Developmental toxicity

#### Glycerol

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

#### 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 (Possibly Carcinogenic to Humans)  
OSHA: Listed

### 12. ECOLOGICAL INFORMATION

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

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Medroxyprogesterone acetate

*Daphnia magna* (Water Flea) EC50 48 Hours 1 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 10 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) EC50 0.13 mg/L

#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### Medroxyprogesterone acetate

Activated sludge EC50 75.4 mg/L

## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 7 of 9

Version: 2.0

### 12. ECOLOGICAL INFORMATION

### 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  
Dangerous for the Environment

**EU Risk Phrases:**

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R40 - Limited evidence of a carcinogenic effect  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**EU Safety Phrases:**

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

**OSHA Label:**

DANGER

May damage fertility or the unborn child.  
Suspected of causing cancer.  
Toxic to aquatic life with long lasting effects.

**Canada - WHMIS: Classifications**

## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 8 of 9

Version: 2.0

### 15. REGULATORY INFORMATION

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A



<b>Citric acid monohydrate</b>	
Australia (AICS):	Present
<b>Glycerol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5
<b>Peppermint oil</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
<b>Sodium citrate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-675-3
<b>Water, purified</b>	
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
<b>Croscarmellose sodium</b>	
Australia (AICS):	Present
<b>Medroxyprogesterone acetate</b>	
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
<b>Methylparaben</b>	
Inventory - United States TSCA - Sect. 8(b)	Present



## MATERIAL SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Oral  
Suspension  
Revision date: 05-Mar-2012

Page 9 of 9

Version: 2.0

### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

#### Propylparaben

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

#### Polysorbate 80

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

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R40 - Limited evidence of a carcinogenic effect

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

**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**