



# SAFETY DATA SHEET

Revision date: 18-Mar-2015

Version: 3.0

Page 1 of 9

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

### Product Identifier

**Material Name:** Medroxyprogesterone Acetate Injectable Suspension, 400 mg/ml

**Trade Name:** DEPO-PROVERA® Sterile Aqueous Suspension

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used for menstrual irregularities

### 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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
International CHEMTREC (24 hours): +1-703-527-3887

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:

R40 - Limited evidence of a carcinogenic effect.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H351 - Suspected of causing cancer  
H360FD - May damage fertility. May damage the unborn child.

**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

## SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
 Suspension, 400 mg/ml  
 Revision date: 18-Mar-2015

Page 2 of 9

Version: 3.0



**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
 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	GHS Classification	%
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.3;R40 Repr. Cat.1;R60-61	Carc. 2 (H351) Repr. 1A (H360FD)	40
Sodium sulfate anhydrous	7757-82-6	231-820-9	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	Acute Tox.3 (H301)	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water	7732-18-5	231-791-2	Not Listed	Not Listed	*

**Additional Information:** \* Proprietary  
 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.

**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 with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

## SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015

Page 3 of 9

Version: 3.0

**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 CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**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

Minimize generating airborne mists and vapors. 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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

## SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015

Page 4 of 9

Version: 3.0

### 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/m<sup>3</sup>, Skin

#### Sodium sulfate anhydrous

Latvia OEL - TWA 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 10 mg/m<sup>3</sup>

#### Polyethylene glycol

Austria OEL - MAKs 1000 mg/m<sup>3</sup>

Germany - TRGS 900 - TWAs 1000 mg/m<sup>3</sup>

Germany (DFG) - MAK 1000 mg/m<sup>3</sup> average molecular weight 200-600

Slovakia OEL - TWA 1000 mg/m<sup>3</sup>

Slovenia OEL - TWA 1000 mg/m<sup>3</sup>

Switzerland OEL - TWAs 1000 ppm

#### Analytical Method:

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

#### 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

#### Color:

Clear

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### 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)

#### Medroxyprogesterone acetate

No data available

#### Water

## SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015

Page 5 of 9

Version: 3.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

#### Myristyl-gamma-picolinium chloride

Predicted 7.4 Log D 1.30

#### Polyethylene glycol

No data available

#### Sodium sulfate anhydrous

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 active ingredient(s).

**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 development of male characteristics in the female fetus

#### Acute Toxicity: (Species, Route, End Point, Dose)

## SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015

Page 6 of 9

Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

#### Medroxyprogesterone acetate

Rat Oral LD50 > 6,400 mg/kg  
Mouse Para-periosteal LD50 376mg/kg  
Rat Intraperitoneal LD50 > 400mg/kg  
Rat Subcutaneous LD50 > 8000mg/kg

#### Myristyl-gamma-picolinium chloride

Rat Oral LD 50 250 mg/kg  
Rat Para-periosteal LD50 30mg/kg  
Rat Intraperitoneal LD50 7500ug/kg  
Rat Subcutaneous LD50 200mg/kg

#### Sodium sulfate anhydrous

Mouse Oral LD50 5989 mg/kg  
Rabbit IV LD50 1220mg/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

##### Polyethylene glycol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### 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

##### Myristyl-gamma-picolinium chloride

60 Day(s) Rat Oral 2400 mg/kg Death

#### 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

## SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015

Page 7 of 9

Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

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)

### 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:**

##### **Partition Coefficient: (Method, pH, Endpoint, Value)**

##### **Myristyl-gamma-picolinium chloride**

Predicted 7.4 Log D 1.30

**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.

# SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015

Page 8 of 9

Version: 3.0

## 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

California Proposition 65

Not Listed

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

#### Sodium sulfate anhydrous

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

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

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

231-820-9

#### Polyethylene glycol

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

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

Present

Australia (AICS):

Present

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 3

EU EINECS/ELINCS List

Not Listed

#### Water

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

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

Present

Australia (AICS):

Present

REACH - Annex IV - Exemptions from the  
obligations of Register:

Present



## SAFETY DATA SHEET

**Material Name: Medroxyprogesterone Acetate Injectable  
Suspension, 400 mg/ml  
Revision date: 18-Mar-2015**

**Page 9 of 9**

**Version: 3.0**

### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	231-791-2
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#### Myristyl-gamma-picolinium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	220-387-1

### 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  
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Carcinogenic: Category 3  
Toxic to reproduction: Category 1  
Xn - Harmful

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect

**Data Sources:** Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

**Revision date:** 18-Mar-2015

**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**