



MATERIAL SAFETY DATA SHEET

Revision date: 06-Apr-2010

Version: 1.2

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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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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ChemSafe (24 hours): +44 (0)208 762 8322

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

Trade Name:	DEPO-PROVERA® Sterile Aqueous Suspension
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used for menstrual irregularities

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid
Signal Word: DANGER

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

Additional Hazard Information:

Short Term:	Not an eye irritant ; Not a skin irritant ; Not acutely toxic (based on animal data) .
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

EU Classification

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

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	%
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.2;R45 Repr. Cat.1;R60-61	40

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Non-hazardous Ingredients	Proprietary	Not listed	Not Listed	*
Water	7732-18-5	231-791-2	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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash off immediately with soap and plenty 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.

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: Not applicable

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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 contact with eyes, skin and clothing. 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.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Medroxyprogesterone acetate

Pfizer OEL TWA-8 Hr:

2 µg/m³, Skin

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. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Rubber gloves
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product. 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
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		

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9. PHYSICAL AND CHEMICAL PROPERTIES

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: None
Incompatible Materials: None

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient(s).

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

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

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

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

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

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11. TOXICOLOGICAL INFORMATION

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

12. ECOLOGICAL INFORMATION

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

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

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

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15. REGULATORY INFORMATION

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)

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

200-757-9

Water

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

Listed

Australia (AICS):

Listed

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.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 3 - Composition / Information on Ingredients.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet