

Revision date: 18-Mar-2015 Version: 5.0 Page 1 of 13

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

**Product Identifier** 

Material Name: Medroxyprogesterone Acetate Suspension - Uniject

Trade Name: DEPO-PROVERA; SAYANA

Synonyms: Medroxyprogesterone Suspension for Injection, Subcutaneous; DEPO-SUBQ PROVERA;

depo-subQ provera 104

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as contraceptive agent

**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

Emergency telephone number:

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

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

# 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:

R60 - May impair fertility.

R61 - May cause harm to the unborn child. R40 - Limited evidence of a carcinogenic effect.

**Label Elements** 

Signal Word: Danger

Hazard Statements: H351 - Suspected of causing cancer

H360FD - May damage fertility. May damage the unborn child.

Material Name: Medroxyprogesterone Acetate Suspension - Page 2 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

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

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)	16
Methionine	63-68-3	200-562-9	Not Listed	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**
Hydrochloric Acid	7647-01-0	231-595-7	T; R23 C; R35	Press. Gas Skin Corr. 1A; H314 Acute Tox. 3; H331	**
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS	EU Classification	GHS Classification	%
		List			
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Sodium Phosphate Monobasic,	10049-21-5	Not Listed	Not Listed	Not Listed	*
Monohydrate					
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Propylparaben Propylparaben	94-13-3	202-307-7	Not Listed	Not Listed	*
Disodium phosphate dodecahydrate	10039-32-4	Not Listed	Not Listed	Not Listed	*

Additional Information: \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has

been withheld as a trade secret.

<sup>\*\*</sup> to adjust pH

Material Name: Medroxyprogesterone Acetate Suspension - Page 3 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

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 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.

Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of** For information on potential signs and symptoms of exposure, See Section 2 - Hazards

**Exposure:** Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Carbon dioxide, carbon monoxide

**Products:** 

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 / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

**Collecting:** area thoroughly.

Additional Consideration for Non-essential personnel should be evacuated from affected area. Report emergency

Large Spills: situations immediately. Clean up operations should only be undertaken by trained personnel.

D704700

Material Name: Medroxyprogesterone Acetate Suspension - Page 4 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

# 7. HANDLING AND STORAGE

## **Precautions for Safe Handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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

## 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/m³, Skin

Methionine

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Sodium hydroxide

**ACGIH Ceiling Threshold Limit:** 2 mg/m<sup>3</sup> **Australia PEAK** 2 mg/m<sup>3</sup> 2 mg/m<sup>3</sup> **Austria OEL - MAKs** 2.0 mg/m<sup>3</sup> **Bulgaria OEL - TWA**  $1 \text{ mg/m}^3$ Czech Republic OEL - TWA Estonia OEL - TWA  $1 \text{ mg/m}^3$ France OEL - TWA  $2 \text{ mg/m}^3$ **Greece OEL - TWA** 2 mg/m<sup>3</sup> 2 mg/m<sup>3</sup> **Hungary OEL - TWA** Japan - OELs - Ceilings 2 ma/m3 Latvia OEL - TWA 0.5 mg/m<sup>3</sup> **OSHA - Final PELS - TWAs:**  $2 \text{ mg/m}^3$ Poland OEL - TWA  $0.5 \text{ mg/m}^{3}$ Slovakia OEL - TWA 2 mg/m<sup>3</sup>  $2 \text{ mg/m}^3$ Slovenia OEL - TWA **Sweden OEL - TWAs**  $1 \text{ mg/m}^3$ **Switzerland OEL -TWAs** 2 mg/m<sup>3</sup>

**Hydrochloric Acid** 

 ACGIH Ceiling Threshold Limit:
 2 ppm

 Australia PEAK
 5 ppm

 7.5 mg/m³
 7.5 mg/m³

 Austria OEL - MAKS
 5 ppm

 8 mg/m³
 5 ppm

 8 mg/m³
 8 mg/m³

 Bulgaria OEL - TWA
 5 ppm

9.0 mg/

8.0 mg/m<sup>3</sup>

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Material Name: Medroxyprogesterone Acetate Suspension - Page 5 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION Cyprus OEL - TWA 5 ppm 8 mg/m<sup>3</sup> Czech Republic OEL - TWA 8 mg/m<sup>3</sup> **Estonia OEL - TWA** 5 ppm 8 mg/m<sup>3</sup> Germany - TRGS 900 - TWAs 2 ppm 3 mg/m<sup>3</sup> 2 ppm Germany (DFG) - MAK 3.0 mg/m<sup>3</sup> **Greece OEL - TWA** 5 ppm 7 mg/m<sup>3</sup> **Hungary OEL - TWA** 8 mg/m<sup>3</sup> **Ireland OEL - TWAs** 5 ppm 8 mg/m<sup>3</sup> 5 ppm **Italy OEL - TWA** 8 mg/m<sup>3</sup> Japan - OELs - Ceilings 5 ppm $7.5 \text{ mg/m}^{3}$ Latvia OEL - TWA 5 ppm 8 mg/m<sup>3</sup> Lithuania OEL - TWA 5 ppm 8 mg/m<sup>3</sup> **Luxembourg OEL - TWA** 5 ppm 8 mg/m<sup>3</sup> 5 ppm Malta OEL - TWA $8 \text{ mg/m}^3$ **Netherlands OEL - TWA** 8 mg/m<sup>3</sup> Poland OEL - TWA 5 mg/m<sup>3</sup> 5 ppm Portugal OEL - TWA 8 mg/m<sup>3</sup> **Romania OEL - TWA** 5 ppm 8 mg/m<sup>3</sup> Slovakia OEL - TWA 5 ppm 8.0 mg/m<sup>3</sup> Slovenia OEL - TWA 5 ppm $8 \text{ mg/m}^3$ Spain OEL - TWA 5 ppm 7.6 mg/m<sup>3</sup> **Switzerland OEL -TWAs** 2 ppm $3.0 \text{ mg/m}^3$ Vietnam OEL - TWAs 5 mg/m<sup>3</sup> Sodium chloride Latvia OEL - TWA 5 mg/m<sup>3</sup> Lithuania OEL - TWA 5 mg/m<sup>3</sup> Polyethylene glycol 1000 mg/m<sup>3</sup> **Austria OEL - MAKs** Germany - TRGS 900 - TWAs 1000 mg/m<sup>3</sup> Germany (DFG) - MAK 1000 mg/m<sup>3</sup> average molecular weight 200-600

1000 mg/m<sup>3</sup>

1000 mg/m<sup>3</sup>

1000 ppm

Slovakia OEL - TWA Slovenia OEL - TWA

**Switzerland OEL -TWAs** 

Material Name: Medroxyprogesterone Acetate Suspension - Page 6 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Molecular Weight:

Mixture

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:Liquid suspensionColor:White to off-whiteOdor:No data available.Odor Threshold:No data available.

Molecular Formula: Mixture

Solvent Solubility:
Water Solubility:
Solubility:
Solubility:
PH:
No data available
Soluble: Water
No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Water for injection
No data available
Polysorbate 80
No data available

Propylparaben
No data available
Methylparaben
No data available

Sodium chloride No data available Polyethylene glycol

Sodium Phosphate Monobasic, Monohydrate

No data available

No data available

Disodium phosphate dodecahydrate

No data available

**Povidone** 

No data available **Hydrochloric Acid** No data available

Material Name: Medroxyprogesterone Acetate Suspension - Page 7 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Sodium hydroxide

No data available Methionine

No data available

Medroxyprogesterone acetate

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

Viscosity:

No data available
No data available
No data available
No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

No data available
No data available
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 No data available

**Products:** 

# 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual

ingredients.

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)

Polysorbate 80

Material Name: Medroxyprogesterone Acetate Suspension - Page 8 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

# 11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 25 g/kg

#### Propylparaben

Mouse Oral LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

#### Sodium chloride

Rat Oral LD50 3000 mg/kg Mouse Oral LD50 4000 mg/kg

#### **Povidone**

Rat Oral LD50 100 g/kg

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

## 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

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)

## Sodium chloride

Eye Irritation Rabbit Moderate Skin Irritation Rabbit Mild

## Polyethylene glycol

Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild

## **Hydrochloric Acid**

Skin Irritation Severe Eye Irritation Severe

#### Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

# Medroxyprogesterone acetate

Eye Irritation Rabbit Non-irritating Skin Irritation Rabbit Mild

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Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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Material Name: Medroxyprogesterone Acetate Suspension - Page 9 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

# 11. TOXICOLOGICAL INFORMATION

#### 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 Intramuscular3 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 Intramuscular3 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 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

**Povidone** 

IARC: Group 3 (Not Classifiable)

**Hydrochloric Acid** 

IARC: Group 3 (Not Classifiable)

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.

Material Name: Medroxyprogesterone Acetate Suspension - Page 10 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

**Toxicity:** No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

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.

## 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

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

Not Listed

carcinogen initial date 1/1/90

developmental toxicity initial date 4/1/90

Present

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Page 11 of 13

Material Name: Medroxyprogesterone Acetate Suspension - Uniject Revision date: 18-Mar-2015 Version: 5.0

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15. REGULATORY INFORMATION	_
Australia (AICS):	Present
EU EINECS/ELINCS List	200-757-9
Methylparaben	
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	202-785-7
Water for injection	
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	Present
obligations of Register:	
EU EINECS/ELINCS List	231-791-2
Povidone	
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	Not Listed
Methionine	
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	200-562-9
Sodium hydroxide	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances	1000 lb
and their Reportable Quantities:	454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	215-185-5
Hydrochloric Acid	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances	5000 lb
and their Reportable Quantities:	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous	500 lb
TPQs	
CERCLA/SARA - Section 302 Extremely Hazardous	5000 lb
Substances EPCRA RQs	

Material Name: Medroxyprogesterone Acetate Suspension - Page 12 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

# 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-595-7

## Sodium 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	231-598-3

## 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	Schedule 3
for Drugs and Poisons:	
EU EINECS/ELINCS List	Not Listed

# Sodium Phosphate Monobasic, Monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

# Polysorbate 80

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	Not Listed

# Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
FU FINECS/FLINCS List	202-307-7

#### Disodium phosphate dodecahydrate

nam phoophate acaccamyarate	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances	5000 lb
and their Reportable Quantities:	2270 kg
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Material Name: Medroxyprogesterone Acetate Suspension - Page 13 of 13

Uniject

Revision date: 18-Mar-2015 Version: 5.0

# **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 Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Acute toxicity, oral-Cat.3; H331 - Toxic if inhaled

C - Corrosive

Carcinogenic: Category 3
Toxic to reproduction: Category 1

T - Toxic

R23 - Toxic by inhalation. R35 - Causes severe burns.

R40 - Limited evidence of a carcinogenic effect

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.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling

and Storage. Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other

Information.

Revision date: 18-Mar-2015

Product Stewardship Hazard Communication

Prepared by: 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** 

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