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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

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

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Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see

Section 8).

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	GHS Classification	%
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. 2 (H351) Repr. 1A (H360FD)	16
Methionine	63-68-3	200-562-9	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*

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

Additional Information: * Proprietary

** to adjust pH

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

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 CLP/GHS abbreviations mentioned in this Section, see Section 16

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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.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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7. HANDLING AND STORAGE

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/m³

Sodium hydroxide

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

Sodium chloride

Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
7.5 mg/m³

 Austria OEL - MAKs
 5 ppm

 8 mg/m³
 8 ppm

 Belgium OEL - TWA
 5 ppm

8 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8. E	XPOSURE CONTROLS / PERSONAL PROTECT	ION
<u></u>	Bulgaria OEL - TWA	5 ppm 8.0 mg/m ³
	Cyprus OEL - TWA	5 ppm 8 mg/m ³
	Czech Republic OEL - TWA	8 mg/m ³
	Estonia OEL - TWA	5 ppm
	Lotonia GEL TWA	8 mg/m ³
	Germany - TRGS 900 - TWAs	2 ppm
	•	3 mg/m ³
	Germany (DFG) - MAK	2 ppm
		3.0 mg/m ³
	Greece OEL - TWA	5 ppm
	Hungary OEL TWA	7 mg/m ³ 8 mg/m ³
	Hungary OEL - TWA Ireland OEL - TWAs	5 ppm
	ileialiu OLL - IWAS	8 mg/m ³
	Italy OEL - TWA	5 ppm
	, v ==	8 mg/m ³
	Japan - OELs - Ceilings	2 ppm
		3.0 mg/m ³
	Latvia OEL - TWA	5 ppm
	LINE OF THE	8 mg/m ³
	Lithuania OEL - TWA	5 ppm 8 mg/m ³
	Luxembourg OEL - TWA	5 ppm
	Editional of the	8 mg/m ³
	Malta OEL - TWA	5 ppm
		8 mg/m ³
	Netherlands OEL - TWA	8 mg/m ³
	Poland OEL - TWA	5 mg/m ³
	Portugal OEL - TWA	5 ppm
	Demonia OFI TWA	8 mg/m ³
	Romania OEL - TWA	5 ppm 8 mg/m ³
	Slovakia OEL - TWA	5 ppm
	Sistana SEE TWA	8.0 mg/m ³
	Slovenia OEL - TWA	5 ppm
		8 mg/m ³
	Spain OEL - TWA	5 ppm
	0 % 1 1051 500	7.6 mg/m ³
	Switzerland OEL -TWAs	2 ppm 3.0 mg/m ³
	Vietnam OEL - TWAs	5.0 mg/m ³
	Vietnam OLL - I WAS	3 mg/m
Polye	ethylene glycol	
	Austria OEL - MAKs	1000 mg/m ³
	Germany - TRGS 900 - TWAs	1000 mg/m ³
	Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
	Slovakia OEL - TWA	1000 mg/m ³
	Slovenia OEL - TWA	1000 mg/m ³
	Switzerland OEL -TWAs	1000 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sodium chloride

Pfizer Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Band (OEB):

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

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment **Equipment:**

supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and

specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug

product is possible and for bulk processing operations. (Protective gloves must meet the

standards in accordance with EN374, ASTM F1001 or international equivalent.)

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the Eyes:

standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact – consider use of disposable

clothing where appropriate. (Protective clothing must meet the standards in accordance with

EN13982, ANSI 103 or international equivalent.)

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection:

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Liquid suspension Color: White to off-white **Physical State:** Odor: No data available. **Odor Threshold:** No data available.

Molecular Formula: Mixture **Molecular Weight:** Mixture

No data available **Solvent Solubility:** 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)

Water for injection No data available Polysorbate 80 No data available Propylparaben No data available Methylparaben

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Sodium chloride

No data available

Polyethylene glycol

No data available

Sodium Phosphate Monobasic, Monohydrate

No data available

Disodium phosphate dodecahydrate

No data available

Povidone

No data available

Hydrochloric Acid

No data available

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:

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.

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11. TOXICOLOGICAL 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 template has resulted in monetrial irregularities (breakthrough blooding, monetrial flow)

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

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

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11. TOXICOLOGICAL INFORMATION

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

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 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

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11. TOXICOLOGICAL INFORMATION

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.

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

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15. REGULATORY INFORMATION

Medroxyprogesterone acetate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 carcinogen 1/1/1990

developmental toxicity 4/1/1990

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

Australia (AICS):

EU EINECS/ELINCS List

Present
200-757-9

Water for injection

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Present

obligations of Register:

EU EINECS/ELINCS List 231-791-2

Methionine

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not

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 Present Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Present Standard for the Uniform Scheduling Schedule 5 for Drugs and Poisons: Schedule 6 **EU EINECS/ELINCS List** 215-185-5

Sodium chloride

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Present

231-598-3

Polysorbate 80

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

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15. REGULATORY INFORMATION

Sodium F	Phosphate	Monobasic.	Monohydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Methylparaben

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Present

202-785-7

Povidone

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

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

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

Polyethylene glycol

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Not Listed

Propylparaben

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Eisted

Not

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15. REGULATORY INFORMATION

Disodium phosphate dodecahydrate

CERCLA/SARA 313 Emission reporting

CERCLA/SARA Hazardous Substances

and their Reportable Quantities:

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

16. OTHER INFORMATION

Text of CLP/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

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 2 - Hazard

Identification. Updated Section 1 - Identification of the Substance/Preparation and the

Company/Undertaking. Updated Section 16 - Other Information. Updated Section 8 - Exposure

Controls / Personal Protection.

Revision date: 17-May-2017

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
