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

Product Identifier

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Medroxyprogesterone Acetate Suspension - Uniject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name</td>
<td>DEPO-PROVERA; SAYANA</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Medroxyprogesterone Suspension for Injection, Subcutaneous; DEPO-SUBQ PROVERA; depo-subQ provera 104</td>
</tr>
<tr>
<td>Chemical Family</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>United Kingdom</td>
</tr>
</tbody>
</table>

Emergency telephone number:

<table>
<thead>
<tr>
<th>CHEMTREC (24 hours): 1-800-424-9300</th>
<th>Emergency telephone number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Ltd +00 44 (0)1304 616161</td>
<td>International CHEMTREC (24 hours): +1-703-527-3887</td>
</tr>
</tbody>
</table>

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

Label Elements

<table>
<thead>
<tr>
<th>Signal Word</th>
<th>Danger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements</td>
<td>H351 - Suspected of causing cancer</td>
</tr>
<tr>
<td></td>
<td>H360FD - May damage fertility. May damage the unborn child.</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone acetate</td>
<td>71-58-9</td>
<td>200-757-9</td>
<td>Carc. 2 (H351) Repr. 1A (H360FD)</td>
<td>16</td>
</tr>
<tr>
<td>Methionine</td>
<td>63-68-3</td>
<td>200-562-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)</td>
<td>**</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

**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**
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 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 CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

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

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
Austria OEL - MAKs 5 ppm
7.5 mg/m³
Belgium OEL - TWA 5 ppm
8 mg/m³

PZ01739
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Location</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.6 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

**Polyethylene glycol**

<table>
<thead>
<tr>
<th>Location</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
</tr>
</tbody>
</table>
| Germany (DFG) - MAK       | 1000 mg/m³ average molecular weight 200-600
| Slovakia OEL - TWA        | 1000 mg/m³   |
| Slovenia OEL - TWA        | 1000 mg/m³   |
| Switzerland OEL - TWAs    | 1000 mg/m³   |

---

**Revision date:** 17-May-2017

**Version:** 6.0
SAFETY DATA SHEET

Material Name: Medroxyprogesterone Acetate Suspension - Uniject
Revision date: 17-May-2017
Version: 6.0
Page 6 of 13

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 Band (OEB):

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

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). Contact your safety and health professional or safety 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.)

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

Respiratory protection: Under normal conditions of use, 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 (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

Physical State: Liquid suspension
Odor: No data available.
Molecular Formula: 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)
Water for injection
No data available
Polysorbate 80
No data available
Propylparaben
No data available
Methylparaben

Color: White to off-white
Odor Threshold: No data available.
Molecular Weight: Mixture
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): 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 individual ingredients.
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 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
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
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
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) Present
  Australia (AICS): Present
  EU EINECS/ELINCS List 200-757-9

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 obligations of Register:
   EU EINECS/ELINCS List 231-791-2

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 for Drugs and Poisons:
   Schedule 5
   Schedule 6
  EU EINECS/ELINCS List 215-185-5

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

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

PZ01739
15. REGULATORY INFORMATION

**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

**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

**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

**Hydrochloric Acid**
- **CERCLA/SARA 313 Emission reporting**: 1.0 %
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 5000 lb, 2270 kg
- **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**: 500 lb
- **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**: 5000 lb
- **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 5, Schedule 6
- **EU EINECS/ELINCS List**: 231-595-7

**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 2, Schedule 3
- **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
- **EU EINECS/ELINCS List**: 202-307-7
15. REGULATORY INFORMATION

Disodium phosphate dodecahydrate

| 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 |

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

Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet