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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Material Name: Methylprednisolone Acetate Suspension, USP, Sterile

- Trade Name: Depo-Medrol
- Chemical Family: Mixture
- Intended Use: Pharmaceutical product used as anti-inflammatory

2. HAZARDS IDENTIFICATION

Appearance: White suspension
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.

Additional Hazard Information:
- Short Term: May be harmful if absorbed through the skin. Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. May produce allergic reactions following skin contact.
- Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs

Known Clinical Effects:
- Adverse clinical reactions include the development of hypersensitivity and/or irritation leading to rashes, itching, and burning. Clinical use has resulted in hormonal alterations. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes.

EU Indication of danger:
- Toxic to reproduction: Category 1

EU Hazard Symbols:

EU Risk Phrases:
- R61 - May cause harm to the unborn child.

Australian Hazard Classification (NOHSC):
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Xn;R20/22</td>
<td>*</td>
</tr>
<tr>
<td>Methylprednisolone Acetate</td>
<td>53-36-1</td>
<td>200-171-3</td>
<td>T;48/22-R61</td>
<td>2-8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<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</td>
<td>7558-80-7</td>
<td>231-449-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>7558-79-4</td>
<td>231-448-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</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>

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: 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.

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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May include oxides of carbon.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Benzyl Alcohol
   - Bulgaria OEL - TWA Listed
   - Czech Republic OEL - TWA Listed
   - Latvia OEL - TWA Listed
   - Lithuania OEL - TWA Listed
   - Poland OEL - TWA Listed

Methylprednisolone Acetate
   - Pfizer OEL TWA-8 Hr: 4µg/m³, Skin

Polyethylene glycol
   - Austria OEL - MAKs Listed
   - Germany - TRGS 900 - TWAs 1000 mg/m³
   - Germany (DFG) - MAK 1000 mg/m³ MAK
   - Slovenia OEL - TWA Listed


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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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: Suspension
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients. The information included in this section describes the potential hazards of various forms of the active ingredient.

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

**Methylprednisolone Acetate**
- Rat Oral LD₅₀ >10,000 mg/m³
- Mouse Sub-tenon injection (eye) LD₅₀ >1,409 mg/kg
- Rat Subcutaneous LD₅₀ 265 mg/kg

**Methylprednisolone**
- Rat Oral LD₅₀ > 2000 mg/kg
- Mouse Oral LD 50 450 mg/kg
- Rat Intraperitoneal LD 50 1000 mg/kg
- Mouse Intraperitoneal LD 50 1409 mg/kg
- Rat Subcutaneous LD 50 >3000 mg/kg

**Polysorbate 80**
- Rat Intravenous LD 50 1790 mg/kg
- Mouse Oral LD 50 25 g/kg
11. TOXICOLOGICAL INFORMATION

**Benzyl Alcohol**
- Rat Oral LD50 1230 mg/kg
- Rat Para-periosteal LD50 53 mg/kg
- Rat Inhalation LC50 46 mg/m³

**Sodium phosphate, dibasic**
- Rat Oral LD50 17 g/kg

**Sodium phosphate, monobasic**
- Rat Oral LD50 8290 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)**

**Methylprednisolone Acetate**
- Eye Irritation Rabbit No effect
- Skin Irritation Rabbit No effect

**Methylprednisolone**
- Skin Irritation Rabbit No effect
- Eye Irritation Rabbit No effect
- Skin Sensitization - GPMT Guinea Pig No effect

**Polyethylene glycol**
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

**Benzyl Alcohol**
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Moderate
- Skin Irritation Guinea Pig Moderate

**Sodium phosphate, dibasic**
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

**Methylprednisolone**
- 42 Day(s) Dog Oral 167 µg/kg/day LOAEL Adrenal gland
- 6 Week(s) Rat Subcutaneous 500 µg/kg/day LOAEL None identified
- 14 Week(s) Rat Subcutaneous 0.4 µg/kg/day NOAEL Blood forming organs, Adrenal gland
- 52 Week(s) Rat Subcutaneous 4 µg/kg/day NOAEL Blood forming organs Adrenal gland

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Methylprednisolone**
- Reproductive & Fertility Rat Subcutaneous 0.004 mg/kg/day NOAEL Paternal toxicity
- Reproductive & Fertility Rat Subcutaneous 0.02 mg/kg/day LOAEL Fetotoxicity
- Embryo / Fetal Development Rat Subcutaneous 1.0 mg/kg/day LOAEL Fetotoxicity, Teratogenic
11. TOXICOLOGICAL INFORMATION

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Methylprednisolone Acetate
Direct DNA Interaction Not applicable Negative
In Vitro Cytogenetics Not applicable Negative

Methylprednisolone
Bacterial Mutagenicity (Ames) Salmonella Negative
Unscheduled DNA Synthesis Rat Hepatocyte Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
Direct DNA Interaction Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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
EU Risk Phrases: R61 - May cause harm to the unborn child.
15. REGULATORY INFORMATION

OSHA Label:
DANGER
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Polysorbate 80
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed

Benzyl Alcohol
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 202-859-9

Sodium phosphate, monobasic
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 231-449-2

Sodium phosphate, dibasic
CERCLA/SARA Hazardous Substances and their Reportable Quantities:

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 231-448-7

Water
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 231-791-2

Methylprednisolone Acetate
Australia (AICS): Listed
EU EINECS/ELINCS List 200-171-3

Polyethylene glycol
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed

PZ01163
## 16. OTHER INFORMATION

**Text of R phrases mentioned in Section 3**

R61 - May cause harm to the unborn child.
R20/22 - Harmful by inhalation and if swallowed.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

**Data Sources:**
Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:**
Not applicable

**Prepared by:**
Toxicology and 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**