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

Material Name: Methylprednisolone, Lidocaine Suspension for Injection

Trade Name:
Depo-Medrol with Lidocaine; Depo-Medrone with Lidocaine

Chemical Family:
Mixture

Intended Use:
Pharmaceutical product used as anti-inflammatory

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

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Mixture

Intended Use:
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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. May cause numbing effects to skin. Accidental ingestion may cause effects similar to those seen in clinical use. May produce allergic reactions following skin contact. (based on animal data).

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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone Acetate</td>
<td>53-36-1</td>
<td>200-171-3</td>
<td>T;48/22-R61</td>
<td>40 mg/mL</td>
</tr>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>73-78-9</td>
<td>200-803-8</td>
<td>Xn;R22</td>
<td>10 mg/mL</td>
</tr>
<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>Myristyl-gamma-picolinium chloride</td>
<td>2748-88-1</td>
<td>220-387-1</td>
<td>Xn;R22</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>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</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>
</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.

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

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

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

Sodium chloride
Latvia OEL - TWA: Listed
Lithuania OEL - TWA: Listed
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lidocaine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)


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.

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LD₅₀</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>50</td>
<td>450 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>50</td>
<td>1000 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>50</td>
<td>1409 mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

**Benzyl Alcohol**
- Rat Intravenous LD50: 53 mg/kg
- Rat Intraperitoneal LD50: 133 mg/kg
- Rat Inhalation LC50: 46 mg/m³

**Lidocaine Hydrochloride**
- Rat Oral LD50: 317 mg/kg
- Rat Intravenous LD50: 25 mg/kg
- Rat Intraperitoneal LD50: 133 mg/kg
- Mouse Oral LD50: 292 mg/kg
- Mouse Intravenous LD50: 19.5 mg/kg

**Sodium chloride**
- Rat Oral LD50: 3000 mg/kg
- Mouse Oral LD50: 4000 mg/kg

**Methylprednisolone Acetate**
- Rat Oral LD50: >10,000 mg/m³
- Mouse Intraperitoneal LD50: >1,409 mg/kg
- Rat Subcutaneous LD50: 265 mg/kg

**Myristyl-gamma-picolinium chloride**
- Rat Oral LD50: 250 mg/kg
- Rat Intravenous LD50: 30 mg/kg
- Rat Intraperitoneal LD50: 7500 µg/kg
- Rat Subcutaneous LD50: 200 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**
- Skin Irritation Rabbit: No effect
- Eye Irritation Rabbit: No effect
- Skin Sensitization - GPMT Guinea Pig: No effect

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

**Lidocaine Hydrochloride**
- Eye Irritation Rabbit: Mild
- Skin Irritation Rabbit: Mild

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

**Sodium chloride**
11. TOXICOLOGICAL INFORMATION

Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

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

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

Myristyl-gamma-picolinium chloride
- 60 Day(s)  Rat  Oral  2400 mg/kg  Death

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
- Embryo / Fetal Development  Mouse  Intramuscular  330 mg/kg/day  LOAEL  Teratogenic
- Embryo / Fetal Development  Rabbit  Intramuscular  0.1 mg/kg/day  LOAEL  Teratogenic

Lidocaine Hydrochloride
- Embryo / Fetal Development  Rat  Subcutaneous  30 mg/kg  NOAEL  Not teratogenic
- Embryo / Fetal Development  Rat  Intraperitoneal  56 mg/kg  NOAEL  Not Teratogenic
- Embryo / Fetal Development  Rat  Intraperitoneal  72 mg/kg/day  NOAEL  Not Teratogenic
- Embryo / Fetal Development  Rat  Intravenous  500 mg/kg/day  LOAEL  Fetotoxicity
- Embryo / Fetal Development  Rat  Intraperitoneal  6 mg/kg  LOAEL  Developmental toxicity

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

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

Lidocaine Hydrochloride
- Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
- In Vitro Chromosome Aberration  Human Lymphocytes  Negative
- In Vivo Micronucleus  Mouse  Negative

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

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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

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

OSHA Label:
DANGER
May damage the unborn child.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
15. REGULATORY INFORMATION

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

Lidocaine Hydrochloride
  Inventory - United States TSCA - Sect. 8(b) Listed
  Australia (AICS): Listed
  EU EINECS/ELINCS List 200-803-8

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

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

Sodium chloride
  Inventory - United States TSCA - Sect. 8(b) Listed
  Australia (AICS): Listed
  EU EINECS/ELINCS List 231-598-3

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

Myristyl-gamma-picolinium chloride
  Inventory - United States TSCA - Sect. 8(b) Listed
  Australia (AICS): Listed
  EU EINECS/ELINCS List 220-387-1

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R22 - Harmful if swallowed.
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.

Prepared by: Toxicology and Hazard Communication
             Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet