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

Product Identifier

Material Name: Methylprednisolone Acetate Injectable Suspension, Single-Dose Vial
Trade Name: DEPO-MEDROL; DEPO-NISOLONE; DEPO-MEDRONE; DEPO-MODERIN; DEPO-MEDOL; DEPO-MEDRATE
Chemical Family: Glucocorticoid

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

Intended Use: Pharmaceutical product used as anti-inflammatory

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

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
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1A
Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements

Signal Word: Danger
Hazard Statements:
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapours-spray
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Version: 3.0

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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Press. Gas</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr.1A (H314)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.3 (H331)</td>
<td></td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>2748-88-1</td>
<td>220-387-1</td>
<td>Acute Tox.3 (H301)</td>
<td>&lt;1.0</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>Methylprednisolone Acetate</td>
<td>53-36-1</td>
<td>200-171-3</td>
<td>Repr.1A (H360D)</td>
<td>4-8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE.2 (H373)</td>
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</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>Polyethylene glycol</td>
<td>25322-68-3</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 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.

PZ01044
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: May include oxides of carbon.

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
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. 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. Releases to the environment should be avoided.

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.

### Hydrochloric Acid

- **ACGIH Ceiling Threshold Limit:** 2 ppm
- **Australia PEAK**
  - 5 ppm
  - 7.5 mg/m³
- **Austria OEL - MAKs**
  - 5 ppm
  - 8 mg/m³
- **Belgium OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Bulgaria OEL - TWA**
  - 5 ppm
  - 8.0 mg/m³
- **Cyprus OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Czech Republic OEL - TWA**
  - 8 mg/m³
- **Estonia OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Germany - TRGS 900 - TWAs**
  - 2 ppm
  - 3 mg/m³
- **Germany (DFG) - MAK**
  - 2 ppm
  - 3.0 mg/m³
- **Greece OEL - TWA**
  - 5 ppm
  - 7 mg/m³
- **Hungary OEL - TWA**
  - 8 mg/m³
- **Ireland OEL - TWAs**
  - 5 ppm
  - 8 mg/m³
- **Italy OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Japan - OELs - Ceilings**
  - 2 ppm
  - 3.0 mg/m³
- **Latvia OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Lithuania OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Luxembourg OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Malta OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Netherlands OEL - TWA**
  - 8 mg/m³
- **Poland OEL - TWA**
  - 5 mg/m³
- **Portugal OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Romania OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Slovakia OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Slovenia OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Spain OEL - TWA**
  - 5 ppm
  - 7.6 mg/m³
SAFETY DATA SHEET

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls
Engineering Controls:
Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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: Suspension
Color: White
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.5 to 7.0
Melting/Freezing Point (°C): No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

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<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
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</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>Methylprednisolone: Predicted 7.4 Log D 1.99</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>Polyethylene glycol: No data available</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>Methylprednisolone Acetate: No data available</td>
</tr>
<tr>
<td>Water for injection</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
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</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
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<tr>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
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</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
<tr>
<td>Polymerization</td>
<td>Will not occur</td>
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</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
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.

Short Term: May be harmful if absorbed through the skin.
11. TOXICOLOGICAL INFORMATION

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus and 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.

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

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

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

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

Myristyl-gamma-picolinium chloride
- Rat Oral LD50 250 mg/kg
- Rat Para-periosteal LD50 30mg/kg
- Rat Intraperitoneal LD50 7500ug/kg
- Rat Subcutaneous LD50 200mg/kg

Sodium hydroxide
- Mouse IP LD50 40 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

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

Methylprednisolone Acetate
- Eye Irritation Rabbit No effect
- Skin Irritation Rabbit No effect
11. TOXICOLOGICAL INFORMATION

Sodium chloride
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Hydrochloric Acid
Skin Irritation  Severe
Eye Irritation  Severe

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

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 & Development Toxicity: (Duration, 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

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

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.

Hydrochloric Acid
IARC:  Group 3 (Not Classifiable)
11. TOXICOLOGICAL INFORMATION

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

Partition Coefficient: (Method, pH, Endpoint, Value)

Methylprednisolone
Predicted 7.4 Log D 1.99

Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30

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

**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**: Present
- **EU EINECS/ELINCS List**: 231-791-2

**Hydrochloric Acid**

- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 1.0 %, 5000 lb, 2270 kg
- **CERCLA/SARA - Section 302 Extremely Hazardous TPQs**: 500 lb
- **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**: 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 5, Schedule 6
- **EU EINECS/ELINCS List**: 231-595-7

**Myristyl-gamma-picolinium 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**: 220-387-1

**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

**Methylprednisolone Acetate**

- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 200-171-3

**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 for Drugs and Poisons**: Schedule 2, Schedule 3
- **EU EINECS/ELINCS List**: Not Listed
15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure if swallowed
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 23-Mar-2017

Prepared by: Product Stewardship 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