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

Product Identifier

Material Name: Methylprednisolone Sodium Succinate for Injection (preservative-free)
Trade Name: Solu-Medrol
Chemical Family: Mixture

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

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements:
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure
May form combustible dust concentrations in air

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/vapors/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 Sodium Succinate for Injection (preservative-free)
Revision date: 22-Jun-2017

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 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone Sodium Succinate</td>
<td>2375-03-3</td>
<td>219-156-8</td>
<td>Repr. 1A (H360D)</td>
<td>67-87</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2 (H373)</td>
<td></td>
</tr>
</tbody>
</table>

**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.**

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.

**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.

Additional Information:
* Proprietary

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16.
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: Formation of toxic gases is possible during heating or fire.

Product:

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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
Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. 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.

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
Methylprednisolone Sodium Succinate
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Powder</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>Soluble: Alcohols</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Sodium phosphate, dibasic No data available</td>
</tr>
<tr>
<td></td>
<td>Sodium phosphate, monobasic No data available</td>
</tr>
<tr>
<td></td>
<td>Lactose                      No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Methylprednisolone Sodium Succinate

No data available

Methylprednisolone

Predicted 7.4  Log D  1.99

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 various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.

Short Term:  May cause eye irritation (based on components). May be harmful if absorbed through the skin.

Long Term:  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. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

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

Methylprednisolone Sodium Succinate

Rat  Oral  LD 50  > 5000 mg/kg
Rat  Para-periosteal  LD 50  718mg/kg
Mouse  Intravenous  LD 50  953mg/kg
Rat  Intraperitoneal  LD 50  512mg/kg
11. TOXICOLOGICAL INFORMATION

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.

Methylprednisolone

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LD 50</th>
<th>MGL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 2000</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>450</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>1000</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>1409</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Subcutaneous</td>
<td>&gt;3000</td>
<td>mg/kg</td>
</tr>
</tbody>
</table>

**Acute Toxicity**

Mouse Intraperitoneal LD 50 902mg/kg

**Rat**

- Oral LD 50 > 2000 mg/kg
- Intraperitoneal LD 50 1000mg/kg
- Subcutaneous LD 50 >3000mg/kg

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

Methylprednisolone

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 Day(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>167 µg/kg/day</td>
<td>LOAEL</td>
<td>Adrenal gland</td>
</tr>
<tr>
<td>6 Week(s)</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>500 µg/kg/day</td>
<td>LOAEL</td>
<td>None identified</td>
</tr>
<tr>
<td>14 Week(s)</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>0.4 µg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Adrenal gland</td>
</tr>
<tr>
<td>52 Week(s)</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>4 µg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs, Adrenal gland</td>
</tr>
</tbody>
</table>

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

Methylprednisolone Sodium Succinate

- Reproductive & Fertility Rat Subcutaneous 40 mg/kg/day LOAEL Fetotoxicity
- Embryo / Fetal Development Rat Subcutaneous 40 mg/kg/day LOAEL Teratogenic

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 Sodium Succinate

- 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.
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 Log D 1.99

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

Lactose
15. REGULATORY INFORMATION

| 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              | 200-559-2 |

Sodium phosphate, dibasic

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb 2270 kg |
| California Proposition 65           | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                  | Present |
| EU EINECS/ELINCS List              | 231-449-7 |

Sodium phosphate, monobasic

| 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              | 231-449-2 |

Methylprednisolone Sodium Succinate

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65           | Not Listed |
| Australia (AICS):                  | Present |
| EU EINECS/ELINCS List              | 219-156-8 |

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

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

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

Revision date: 22-Jun-2017
Product Stewardship Hazard Communication


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