# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Methylprednisolone Tablets**

**Trade Name:** MEDROL
**Chemical Family:** Corticosteroid hormone

**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**

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

**Pfizer Ltd**
**Ramsgate Road**
**Sandwich, Kent**
**CT13 9NJ**
**United Kingdom**
**+00 44 (0)1304 616161**
**Emergency telephone number:**
**Animal Health Division (office hours): +44 (0)1737 331333**

## 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:**
H360 - May damage fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure: blood and blood forming organs, adrenal gland

**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
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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 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

**Hazardous**

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---|---|---|---|---|
| Methylprednisolone | 83-43-2 | 201-476-4 | Repr. 1A (H360)<br>STOT RE 2 (H373) | 4 |
| Corn Starch | 9005-25-8 | 232-679-6 | Not Listed | * |
| Sucrose | 57-50-1 | 200-334-9 | Not Listed | * |
| Calcium stearate | 1592-23-0 | 216-472-8 | Not Listed | * |
| Mineral oil | 8012-95-1 | 232-384-2 | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---|---|---|---|---|
| Sorbic acid | 110-44-1 | 203-768-7 | Not Listed | * |
| Lactose | 63-42-3 | 200-559-2 | Not Listed | * |

**Additional Information:** * Proprietary
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 eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and 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:** May include oxides of carbon.

**Fire / Explosion Hazards:** Not applicable

**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. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Methylprednisolone**

| | |
|---|---|
| **Pfizer OEL TWA-8 Hr:** | 4 µg/m$^3$, Skin |

**Corn Starch**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Australia TWA** | 10 mg/m$^3$ |
| **Belgium OEL - TWA** | 10 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 10.0 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 4.0 mg/m$^3$ |
| **Greece OEL - TWA** | 10 mg/m$^3$<br>5 mg/m$^3$ |
| **Ireland OEL - TWAs** | 10 mg/m$^3$<br>4 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 15 mg/m$^3$ |
| **Portugal OEL - TWA** | 10 mg/m$^3$ |
| **Slovakia OEL - TWA** | 4 mg/m$^3$ |
| **Spain OEL - TWA** | 10 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 3 mg/m$^3$ |

**Sucrose**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Australia TWA** | 10 mg/m$^3$ |
| **Belgium OEL - TWA** | 10 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 10.0 mg/m$^3$ |
| **Estonia OEL - TWA** | 10 mg/m$^3$ |
| **France OEL - TWA** | 10 mg/m$^3$ |
| **Ireland OEL - TWAs** | 10 mg/m$^3$ |
| **Latvia OEL - TWA** | 5 mg/m$^3$ |
| **Lithuania OEL - TWA** | 10 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 15 mg/m$^3$ |
| **Portugal OEL - TWA** | 10 mg/m$^3$ |
| **Slovakia OEL - TWA** | 6 mg/m$^3$ |
| **Spain OEL - TWA** | 10 mg/m$^3$ |

**Calcium stearate**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Lithuania OEL - TWA** | 5 mg/m$^3$ |
| **Sweden OEL - TWAs** | 5 mg/m$^3$ |

**Mineral oil**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 5 mg/m$^3$ |
| **Australia TWA** | 5 mg/m$^3$ |
| **Belgium OEL - TWA** | 5 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 5.0 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 5 mg/m$^3$ |
| **Denmark OEL - TWA** | 1 mg/m$^3$ |
| **Finland OEL - TWA** | 5 mg/m$^3$ |
| **Greece OEL - TWA** | 5 mg/m$^3$ |
| **Lithuania OEL - TWA** | 1 mg/m$^3$ |
| **Netherlands OEL - TWA** | 5 mg/m$^3$ |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **OSHA - Final PELS - TWAs:** | 5 mg/m$^3$ |
| **Poland OEL - TWA** | 5 mg/m$^3$ |
| **Portugal OEL - TWA** | 5 mg/m$^3$ |
| **Romania OEL - TWA** | 5 mg/m$^3$ |
| **Slovakia OEL - TWA** | 5 ppm |
| | 1 mg/m$^3$ |
| | 5 mg/m$^3$ |
| **Spain OEL - TWA** | 5 mg/m$^3$ |
| **Sweden OEL - TWAs** | 1 mg/m$^3$ |
| **Vietnam OEL - TWAs** | 5 mg/m$^3$ |

**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:** | Tablets | **Color:** | Various |
| **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:** | No data available. |
| **Melting/Freezing Point (°C):** | No data available |
| **Boiling Point (°C):** | No data available. |

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

**Calcium stearate**
No data available

**Sucrose**
No data available

**Corn Starch**
No data available

**Lactose**

## 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Sorbic acid**

No data available

**Mineral oil**

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

**Flammablity:**

**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.
**Short Term:** May be absorbed through the skin and cause systemic effects.
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs. May cause allergic reactions in susceptible individuals following repeated contact with this material.
**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.

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

**Sucrose**

Rat Oral LD50 29.7 g/kg

**Sorbic acid**

Rat Oral LD50 7360 mg/kg

## 11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 3200mg/kg

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

**Mineral oil**
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

**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

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

**Sucrose**
Bacterial Mutagenicity (Ames) *Salmonella* 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 thoroughly investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Methylprednisolone**
Predicted 7.4 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**

**Methylprednisolone**
**CERCLA/SARA 313 Emission reporting** Not Listed

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **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 4 |
| **EU EINECS/ELINCS List** | 201-476-4 |

**Corn Starch**

| | |
|---|---|
| **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** | 232-679-6 |

**Sucrose**

| | |
|---|---|
| **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** | 200-334-9 |

**Calcium stearate**

| | |
|---|---|
| **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** | 216-472-8 |

**Mineral oil**

| | |
|---|---|
| **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** | 232-384-2 |

**Sorbic acid**

| | |
|---|---|
| **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** | 203-768-7 |

**Lactose**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **REACH - Annex IV - Exemptions from the obligations of Register:** | Present |
| **EU EINECS/ELINCS List** | 200-559-2 |

## 16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Reproductive toxicity-Cat.1A; H360 - May damage fertility or the unborn child
Specific target organ toxicity, single exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

| | |
|---|---|
| **Data Sources:** | Pfizer proprietary drug development information. Publicly available toxicity information. |
| **Reasons for Revision:** | Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 2 - Hazard Identification. |
| **Revision date:** | 23-Mar-2017 |
| **Prepared by:** | Product Stewardship Hazard Communication<br>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**