



MATERIAL SAFETY DATA SHEET

Revision date: 09-Apr-2010

Version: 1.4

Page 1 of 8

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

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:
ChemSafe (24 hours): +44 (0)208 762 8322

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:

**Australian Hazard Classification
(NOHSC):**

R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 2 of 8

Version: 1.4

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

Hazardous

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Polysorbate 80	9005-65-6	Not listed	Not Listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*

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.

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 3 of 8

Version: 1.4

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/m ³ , Skin
----------------------	---------------------------

Polyethylene glycol

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ MAK
Slovenia OEL - TWA	Listed

Analytical Method: Analytical method available for methylprednisolone. Contact Pfizer Inc for further information.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 4 of 8

Version: 1.4

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	Color:	White
Molecular Formula:	Mixture	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/m ³
Mouse	Sub-tenon injection (eye)	LD50	>1,409 mg/kg
Rat	Subcutaneous	LD50	265 mg/kg

Methylprednisolone

Rat	Oral	LD 50	> 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

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 5 of 8

Version: 1.4

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 LD 50 17 g/kg

Sodium phosphate, monobasic

Rat Oral LD 50 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

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 6 of 8

Version: 1.4

11. TOXICOLOGICAL INFORMATION

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 Acetate

Direct DNA Interaction	Not applicable	Negative
<i>In Vitro</i> Cytogenetics	Not applicable	Negative

Methylprednisolone

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	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.

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

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 7 of 8

Version: 1.4

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:	2270 kg final RQ 5000 lb final RQ
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:	Present
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

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Suspension, USP,
Sterile
Revision date: 09-Apr-2010

Page 8 of 8

Version: 1.4

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