



MATERIAL SAFETY DATA SHEET

Revision date: 06-Sep-2012

Version: 1.1

Page 1 of 9

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
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International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Methylprednisolone Acetate Injectable Suspension, Single-Dose Vial

Trade Name: DEPO-MEDROL
Chemical Family: Glucocorticoid
Intended Use: Pharmaceutical product used as anti-inflammatory

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.

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

EU Indication of danger: Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:

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

Australian Hazard Classification (NOHSC):

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.

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 2 of 9

Version: 1.1

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Methylprednisolone Acetate	53-36-1	200-171-3	T;48/22-R61	4-8
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

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.

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 3 of 9

Version: 1.1

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. 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.
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/m ³ , Skin
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sodium hydroxide	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 4 of 9

Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydrochloric Acid

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

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 5 of 9

Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
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:	Solution	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	3.5 to 7.0		
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

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

Methylprednisolone Acetate

MATERIAL SAFETY DATA SHEET

**Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012**

Page 6 of 9

Version: 1.1

11. TOXICOLOGICAL INFORMATION

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Myristyl-gamma-picolinium chloride

Rat Oral LD 50 250 mg/kg
Rat Para-periosteal LD50 30 mg/kg
Rat Intraperitoneal LD50 7500 ug/kg
Rat Subcutaneous LD50 200 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 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

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Hydrochloric Acid

Skin Irritation Severe
Eye Irritation Severe

Sodium chloride

Eye Irritation Rabbit Moderate
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

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 7 of 9

Version: 1.1

11. TOXICOLOGICAL INFORMATION

52 Week(s) Rat Subcutaneous 4 µg/kg/day NOEL 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	NOEL	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)	<i>Salmonella</i>	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
<i>In Vitro</i> 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)

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

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 8 of 9

Version: 1.1

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

OSHA Label:
DANGER
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Methylprednisolone Acetate	
Australia (AICS):	Present
EU EINECS/ELINCS List	200-171-3
Myristyl-gamma-picolinium chloride	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	220-387-1
Sodium chloride	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
Water for injection	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present

MATERIAL SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 06-Sep-2012

Page 9 of 9

Version: 1.1

15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-791-2

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb
454 kg
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
EU EINECS/ELINCS List 215-185-5

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb
2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs 500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs 5000 lb
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
EU EINECS/ELINCS List 231-595-7

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3

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: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification.

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