



MATERIAL SAFETY DATA SHEET

Revision date: 06-Apr-2010

Version: 2.0

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

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Material Name: Methylprednisolone Tablets

Trade Name:	MEDROL
Chemical Family:	Corticosteroid hormone
Intended Use:	Pharmaceutical active used as anti-inflammatory

2. HAZARDS IDENTIFICATION

Appearance: Tablets, varying in color depending on strength
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.
May cause damage to blood and blood forming organs through prolonged or repeated exposure.

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.

EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Hazard Symbols:



EU Risk Phrases: R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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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	%
Methylprednisolone	83-43-2	201-476-4	T;R48/22 Repr.Cat.1;R61	2, 4, 8, 16 or 32mg***
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Mineral oil	8012-95-1	232-384-2	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*

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

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: Not applicable

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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 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.
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:	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.
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

Pfizer OEL TWA-8 Hr: 4 µg/m³, Skin

Calcium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Mineral oil

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	5 mg/m ³ TWA
ACGIH Threshold Limit Value (STEL)	10 mg/m ³ STEL
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	5 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	5 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Spain 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.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	Various
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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.

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

Sucrose

Rat Oral LD50 29.7 g/kg

Lactose

Rat Oral LD50 > 10 g/kg

Sorbic acid

Rat Oral LD50 7360 mg/kg

Mouse Oral LD50 3200 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

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)

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11. TOXICOLOGICAL INFORMATION

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)

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.

Mineral oil
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly 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.

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15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Risk Phrases:
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
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.
May cause damage to blood and blood forming organs through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials



Methylprednisolone

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	201-476-4

Calcium stearate

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	216-472-8

Corn Starch

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	232-679-6

Lactose

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-559-2

Mineral oil

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-384-2

Sorbic acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	203-768-7

Sucrose

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	200-334-9

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

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: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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