



SAFETY DATA SHEET

Revision date: 23-Mar-2017

Version: 3.0

Page 1 of 11

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

Product Identifier

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

Trade Name: DEPO-MEDROL; DEPO-NISOLONE; DEPO-MEDRONE; DEPO-MODERIN; DEPO-MEDOL;
DEPO-MEDRATE

Chemical Family: Glucocorticoid

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
Contact E-Mail: pfizer-MSDS@pfizer.com

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

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: H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

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 Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 2 of 11

Version: 3.0



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	%
Hydrochloric Acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	<1.0
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Acute Tox.3 (H301)	<1.0
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Methylprednisolone Acetate	53-36-1	200-171-3	Repr.1A (H360D) STOT RE.2 (H373)	4-8

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS 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. 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 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.

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 3 of 11

Version: 3.0

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

Medical Conditions Aggravated by Exposure: Identification and/or Section 11 - Toxicological Information.

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: 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 spill with absorbent material. 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

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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 4 of 11

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

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	5 ppm
	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	2 ppm
	3.0 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
Portugal OEL - TWA	5 ppm
	8 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

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 5 of 11

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Methylprednisolone Acetate	
Pfizer OEL TWA-8 Hr:	4µg/m ³ , Skin
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
Switzerland OEL -TWAs	1000 mg/m ³
Sodium chloride	
Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³)
Exposure Controls	
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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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:	Suspension	Color:	White
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:	3.5 to 7.0		
Melting/Freezing Point (°C):	No data available		

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 6 of 11

Version: 3.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.

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

Methylprednisolone

Predicted 7.4 Log D 1.99

Polyethylene glycol

No data available

Methylprednisolone Acetate

No data available

Water for injection

No data available

Sodium chloride

No data available

Myristyl-gamma-picolinium chloride

Predicted 7.4 Log D 1.30

Hydrochloric Acid

No data available

Sodium hydroxide

No data available

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

Polymerization: Will not occur

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 No data available

Products:

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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.

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

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 7 of 11

Version: 3.0

11. TOXICOLOGICAL INFORMATION

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.

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

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

Methylprednisolone Acetate

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

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Myristyl-gamma-picolinium chloride

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

Sodium hydroxide

Mouse IP LD50 40 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

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 8 of 11

Version: 3.0

11. TOXICOLOGICAL INFORMATION

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Hydrochloric Acid

Skin Irritation Severe
Eye Irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

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	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

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)

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 9 of 11

Version: 3.0

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	7.4	Log D	1.99	

Myristyl-gamma-picolinium chloride

Predicted	7.4	Log D	1.30	
-----------	-----	-------	------	--

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

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 10 of 11

Version: 3.0

15. REGULATORY INFORMATION

Water for injection

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	231-791-2

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

Myristyl-gamma-picolinium chloride

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	220-387-1

Sodium chloride

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	231-598-3

Methylprednisolone Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	200-171-3

Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
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 2
EU EINECS/ELINCS List	Schedule 3
	Not Listed

SAFETY DATA SHEET

Material Name: Methylprednisolone Acetate Injectable
Suspension, Single-Dose Vial
Revision date: 23-Mar-2017

Page 11 of 11

Version: 3.0

15. REGULATORY INFORMATION

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 if swallowed

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

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

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

Revision date: 23-Mar-2017

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