



SAFETY DATA SHEET

Revision date: 21-Nov-2014

Version: 4.0

Page 1 of 10

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

Product Identifier

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Trade Name: Solu-Medrol; Solu-Medrone; Solu-Moderin

Chemical Family: Mixture

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

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A

Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

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

EU Risk Phrases:

R61 - May cause harm to the unborn child.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Label Elements

Signal Word: Danger

Hazard Statements: H373 - May cause damage to organs through prolonged or repeated exposure H360D - May damage the unborn child
May form combustible dust concentrations in air

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Revision date: 21-Nov-2014

Page 2 of 10

Version: 4.0

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



Other Hazards

Australian Hazard Classification (NOHSC):

No data available

Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0
Methylprednisolone Sodium Succinate	2375-03-3	219-156-8	Repr.Cat.1;R61 Xn;R48/22	Repr. 1A (H360D) STOT RE 2 (H373)	67-87

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium phosphate, monobasic	7558-80-7	231-449-2	Not Listed	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP
Revision date: 21-Nov-2014

Page 3 of 10

Version: 4.0

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.
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
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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:	Formation of toxic gases is possible during heating or fire.
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 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

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP
Revision date: 21-Nov-2014

Page 4 of 10

Version: 4.0

7. HANDLING AND STORAGE

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. 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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Methylprednisolone Sodium Succinate

Pfizer OEL TWA-8 Hr: 4 µg/m³, Skin

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).
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:	Powder	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	Soluble: Alcohols		
Water Solubility:	No data available		
Solubility:	Soluble: Water		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP
Revision date: 21-Nov-2014

Page 5 of 10

Version: 4.0

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Sodium phosphate, dibasic

No data available

Sodium phosphate, monobasic

No data available

Lactose

No data available

Methylprednisolone Sodium Succinate

No data available

Methylprednisolone

Predicted 7.4 Log D 1.99

Benzyl Alcohol

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

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 various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.

Short Term:

May cause eye irritation (based on components) . May be harmful if absorbed through the skin.

Long Term:

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. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Revision date: 21-Nov-2014

Page 6 of 10

Version: 4.0

11. TOXICOLOGICAL INFORMATION

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

Methylprednisolone Sodium Succinate

Rat	Oral	LD 50	> 5000 mg/kg
Rat	Para-periosteal	LD 50	718mg/kg
Mouse	Intravenous	LD 50	953mg/kg
Rat	Intraperitoneal	LD 50	512mg/kg
Mouse	Intraperitoneal	LD 50	902mg/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

Benzyl Alcohol

Rat	Oral	LD50	1230 mg/kg
Rat	Para-periosteal	LD50	53mg/kg
Rat	Inhalation	LC50	>4.178mg/L

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

Benzyl Alcohol

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Minimal
Skin Irritation	Guinea Pig	Moderate

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 Sodium Succinate

Reproductive & Fertility	Rat	Subcutaneous	40 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	40 mg/kg/day	LOAEL	Teratogenic

Methylprednisolone

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Revision date: 21-Nov-2014

Page 7 of 10

Version: 4.0

11. TOXICOLOGICAL INFORMATION

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 Sodium Succinate

Direct DNA Interaction Not applicable Negative

In Vitro Cytogenetics Not applicable 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.

12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzyl Alcohol

Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 460 mg/L

Daphnia magna (Water Flea) OECD EC50 48 Hours 230 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 500 mg/L

Benzyl Alcohol

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Benzyl Alcohol

OECD Activated sludge Ready 92% After 14 Day(s) Ready

Bio-accumulative Potential:

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

Methylprednisolone

Predicted 7.4 Log D 1.99

Mobility in Soil:

No data available

SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Revision date: 21-Nov-2014

Page 8 of 10

Version: 4.0

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Benzyl Alcohol

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	202-859-9

Sodium phosphate, monobasic

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	231-449-2

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
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SAFETY DATA SHEET

Material Name: Methylprednisolone Sodium Succinate for Injection, USP

Revision date: 21-Nov-2014

Page 9 of 10

Version: 4.0

15. REGULATORY INFORMATION

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
California Proposition 65	2270 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Present
	231-448-7

Lactose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2

Methylprednisolone Sodium Succinate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	219-156-8

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Xn - Harmful

Toxic to reproduction: Category 1

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

Revision date: 21-Nov-2014

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

SAFETY DATA SHEET

**Material Name: Methylprednisolone Sodium Succinate for
Injection, USP**

Revision date: 21-Nov-2014

Page 10 of 10

Version: 4.0

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