SAFETY DATA SHEET

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

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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:
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

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

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

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

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	%
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0
Methylprednisolone Sodium Succinate	2375-03-3	219-156-8	Repr. 1A (H360D) STOT RE 2 (H373)	67-87

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose	63-42-3	200-559-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	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 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.

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

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 firefighting 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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	40 µg/m^3

Sodium phosphate, dibasic

Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

Sodium phosphate, monobasic

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. 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are 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:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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.
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

Flammablity:
- **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.

11. TOXICOLOGICAL INFORMATION

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.

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

11. TOXICOLOGICAL INFORMATION

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
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

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

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

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

15. REGULATORY INFORMATION

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

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

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 CLP/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

Data Sources:	Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	25-Sep-2019
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet