MATERIAL SAFETY DATA SHEET

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

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Material Name: Methylprednisolone, Lidocaine Suspension for Injection

Trade Name: Depo-Medrol with Lidocaine; Depo-Medrone with Lidocaine
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anti-inflammatory

2. HAZARDS IDENTIFICATION

Appearance: White suspension
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.

Additional Hazard Information:

Short Term: May be harmful if absorbed through the skin. May cause numbing effects to skin . Accidental ingestion may cause effects similar to those seen in clinical use. May produce allergic reactions following skin contact. (based on animal data) .

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. 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. 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:

T

EU Risk Phrases:

R61 - May cause harm to the unborn child.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	Classification	%
Methylprednisolone Acetate	53-36-1	200-171-3	T;48/22-R61	40 mg/mL
Lidocaine Hydrochloride	73-78-9	200-803-8	Xn;R22	10 mg/mL
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	*
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water	7732-18-5	231-791-2	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 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.

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. 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.

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

Benzyl Alcohol

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Poland OEL - TWA	Listed

Polyethylene glycol

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m^3
Germany (DFG) - MAK	1000 mg/m^3 MAK
Slovenia OEL - TWA	Listed

Sodium chloride

Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lidocaine Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m^3 to < 1000ug/m^3)

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Suspension	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Rat Subcutaneous LD 50 >3000 mg/kg

Benzyl Alcohol
Rat Oral LD50 1230 mg/kg
Rat Intravenous LD50 53 mg/kg
Rat Inhalation LC50 46 mg/m^3

Lidocaine Hydrochloride
Rat Oral LD50 317 mg/kg
Rat Intravenous LD50 25 mg/kg
Rat Intraperitoneal LD50 133 mg/kg
Mouse Oral LD50 292 mg/kg
Mouse Intravenous LD50 19.5 mg/kg

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

Methylprednisolone Acetate
Rat Oral LD50 >10,000 mg/m^3
Mouse Intraperitoneal LD50 >1,409 mg/kg
Rat Subcutaneous LD50 265 mg/kg

Myristyl-gamma-picolinium chloride
Rat Oral LD 50 250 mg/kg
Rat Intravenous LD50 30 mg/kg
Rat Intraperitoneal LD50 7500 ug/kg
Rat Subcutaneous LD50 200 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

Benzyl Alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

Lidocaine Hydrochloride
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Methylprednisolone Acetate
Eye Irritation Rabbit No effect
Skin Irritation Rabbit No effect

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 & 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

Lidocaine Hydrochloride
Embryo / Fetal Development Rat Subcutaneous 30 mg/kg NOAEL Not teratogenic
Embryo / Fetal Development Rat Intraperitoneal 56 mg/kg NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 72 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intravenous 500 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal 6 mg/kg LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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

Lidocaine Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Negative

Methylprednisolone Acetate
Direct DNA Interaction Not applicable Negative
In Vitro Cytogenetics Not applicable Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

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:

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

OSHA Label:
DANGER
May damage the unborn child.

Canada - WHMIS: Classifications

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

15. REGULATORY INFORMATION

Methylprednisolone Acetate

Australia (AICS):	Listed
EU EINECS/ELINCS List	200-171-3

Lidocaine Hydrochloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-803-8

Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-859-9

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-598-3

Water

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	231-791-2

Myristyl-gamma-picolinium chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	220-387-1

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
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: Pfizer proprietary drug development information. Publicly available toxicity information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet