



MATERIAL SAFETY DATA SHEET

Revision date: 18-Mar-2011

Version: 1.0

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

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Material Name: Dexamethasone Sodium Phosphate Injection, USP

Trade Name:	Not applicable
Synonyms:	Dexamethasone Sodium Phosphate USP
Chemical Family:	Corticosteroid hormone
Intended Use:	Pharmaceutical product used as

2. HAZARDS IDENTIFICATION

Appearance: Aqueous sterile solution
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.

Known Clinical Effects: Clinical use may cause an increase in blood pressure (hypertension). Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. 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.

EU Indication of danger: Toxic to reproduction, Category 2

EU Hazard Symbols:



EU Risk Phrases:

R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Additional Information:
Note:

For a more detailed discussion of potential health hazards and toxicity see Section 11. 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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Dexamethasone Sodium Phosphate	2392-39-4	219-243-0	Repr.Cat.2;R61 Xn;R22	1.0
Citric acid	77-92-9	201-069-1	Xi; R36	**
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Propylparaben	94-13-3	202-307-7	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium citrate, anhydrous	68-04-2	200-675-3	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Edetate disodium	139-33-3	205-358-3	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

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 and fluorine
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.

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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 the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to
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 hands and any exposed skin after removal of PPE. 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.

Dexamethasone Sodium Phosphate	
Pfizer OEL TWA-8 Hr:	3.0µg/m ³
Sodium hydroxide	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	Aqueous solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

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. The information included in this section describes the potential hazards of the active ingredient and/or of a chemically-related material.

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

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Edetate disodium

Rat Oral LD50 2000-2200 mg/kg

Dexamethasone

Rat Oral LD 50 > 3000 mg/kg
Rat Sub-tenon injection (eye) LD 50 54 mg/kg
Rat Subcutaneous LD 50 14 mg/kg
Mouse Intraperitoneal LD 50 410 mg/kg
Mouse Subcutaneous LD 50 4400 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

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11. TOXICOLOGICAL INFORMATION

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Dexamethasone Sodium Phosphate

Mouse Oral LD50 1800

Mouse Sub-tenon injection (eye) LD50 550

Mouse Intravenous LD50 932

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)

Dexamethasone

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Citric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

Dexamethasone

90 Day(s) Rat Oral 0.003 mg/kg/day LOAEL Adrenal gland

13 Week(s) Rat Subcutaneous 40 µg/kg/day LOAEL Adrenal gland, Thymus

26 Week(s) Rat Oral 0.125 mg/kg/day LOAEL Thymus, Adrenal gland

6 Week(s) Dog Oral 0.125 mg/kg/day LOAEL Adrenal gland

26 Week(s) Dog Oral 2 mg/kg/day LOAEL Adrenal gland, Thymus

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Dexamethasone

Embryo / Fetal Development Mouse Subcutaneous 0.15 mg/kg/day LOAEL Teratogenic

Embryo / Fetal Development Rat Subcutaneous 1 mg/kg/day NOAEL Teratogenic

Embryo / Fetal Development Rabbit Intramuscular 0.025 mg/kg/day NOAEL Teratogenic

Embryo / Fetal Development Rabbit Subcutaneous 0.02 mg/kg/day LOAEL Maternal Toxicity, Teratogenic

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

Dexamethasone

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vitro Mammalian Cell Mutagenicity Rat Negative

In Vivo Micronucleus Mouse Equivocal

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11. TOXICOLOGICAL INFORMATION

Chromosome Aberration Human Lymphocytes Positive
Sister Chromatid Exchange Human Lymphocytes Positive

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 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

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

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2

EU Risk Phrases:
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May damage the unborn child.

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

WHMIS hazard class:

D2a very toxic materials



Dexamethasone Sodium Phosphate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	219-243-0

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-307-7

Water for injection

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

Sodium citrate, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	200-675-3

Citric acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-069-1

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ
	454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	215-185-5

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-785-7

Edetate disodium

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	205-358-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R61 - May cause harm to the unborn child.

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

Prepared by: Product Stewardship Hazard Communications
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