SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Dexamethasone Sodium Phosphate Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure:
Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: May cause irritation.

Signs/Symptoms:
Glucocorticoids may cause profound and varied metabolic effects and modify the body's immune responses.

Side effects from therapeutic doses include: sodium and fluid retention, congestive heart failure (in susceptible patients), hypokalemia, hypertension, muscle weakness, osteoporosis, fractures, peptic ulcer, perforation of the large and small bowel, pancreatitis, impaired wound healing, skin reactions, convulsions, headache, vertigo, cushingoid state, cataracts, glaucoma, weight gain, increased appetite, nausea, malaise and hiccups.

Occupational exposure has not been fully investigated.?

Aggravation of Pre-Existing Conditions:
Pre-existing skin and respiratory conditions. Hypersensitivity to any component of the product, including sulfites. Sodium bisulfite may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. Therapeutic use of corticosteroids may exacerbate systematic fungal infections and should not be used in the presence of such infections.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Dexamethasone Phosphate	2392-39-4	4 mg/mL or 10 mg/mL	
Benzyl Alcohol	100-51-6	10 mg/mL in preserved product	
Sodium Sulfite	7757-83-7	See package insert	
Sodium Citrate Dihydrate	6132-04-3	See package insert	
Water for Injection	7732-18-5	Quantity Sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Sensitive to heat. Do not autoclave. Protect from freezing. Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Clear to pale yellow
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.0 - 8.5
Molecular Formula:	Mixture
Molecular Weight:	516.41
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from light and excessive heat. Do not autoclave. Do not freeze.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	ACUTE EFFECTS: In the event of an overdose, no specific antidote is available. Treatment is supportive and symptomatic.

Dexamethasone Phosphate :

Acute Toxicity:	LD50: IV Female Mouse 794 mg/kg
Acute Effects:	In the event of an overdose, no specific antidote is available. Treatment is supportive and symptomatic.
Chronic Effects:	Prolonged exposure may result in subcasular cataracts, glaucoma, hypertension, salt and water retention, and hypokalemia.
Teratogenicity:	Pregnancy Category C. Use of dexamethasone sodium phosphate in pregnancyrequires that the anticipated benefits be weighed against the potential risks to the mother and fetus.

Dexamethasone Phosphate :

RTECS Number:	TU4056000
Ingestion:	Oral - Mouse LD50: 1800 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 932 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat TDLo: 5 mg/kg/2W (intermittent) [Cardiac - other changes Vascular - BP elevation not characterized in autonomic section Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - proteases] Subcutaneous - Mouse TDLo: 12800 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g.

dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse LD50: 550 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 0.2 mg/kg [Gastrointestinal - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other Enzymes Biochemical - Metabolism (Intermediary) - histamines (including liberation not immunochemical in origin)]
Intraperitoneal. - Rat TDLo: 1 mg/kg [Vascular - BP elevation not characterized in autonomic section]
Intraperitoneal. - Guinea pig TDLo: 340 mg/kg/17D (intermittent) [Lungs, Thorax, or Respiration - other changes Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
Intraperitoneal. - Rat TDLo: 400 ug/kg [Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]

Benzyl Alcohol :

RTECS Number: DN3150000

Skin: Administration onto the skin - Rabbit LD50: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H
Administration onto the skin - Rat LD50: 100 pph/90M [Details of toxic effects not reported other than lethal dose value]

Inhalation: Inhalation - Mouse LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Inhalation - Rat LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]

Ingestion: Oral - Rat LD50: 1230 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma]
Oral - Mouse LD50: 1360 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 1360 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Oral - Rat LD50: 1660 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Oral - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Rat LD50: 53 mg/kg [Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat LDLo: 1700 mg/kg [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - coma Kidney/Ureter/Bladder - other changes]
Intraperitoneal. - Rat LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 650 mg/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea]
Intraperitoneal. - Rat LDLo: 650 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Intraperitoneal. - Rat TDLo: 514 mg/kg [Behavioral - ataxia]

Sodium Sulfite :

RTECS Number: WE2150000

Ingestion: Oral - Rat LD50: 3560 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Convulsions or effect on seizure threshold Skin and Appendages - Hair]
Oral - Mouse LD50: 820 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 175 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - respiratory depression Lungs, Thorax, or Respiration - other changes]
Intravenous. - Guinea pig LDLo: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit LDLo: 600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Guinea pig LDLo: 600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 950 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Dexamethasone Phosphate :

TSCA Inventory Status: Listed

EINECS Number: 219-243-0

Canada DSL:	Listed

Benzyl Alcohol :

TSCA Inventory Status:	Listed
EINECS Number:	202-859-9
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

Sodium Sulfite :

TSCA Inventory Status:	Listed
EINECS Number:	231-821-4
Canada DSL:	Listed

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

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Disclaimer:

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