(M)SDS Format : GHS

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FRESENIUS KABI

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SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Methylprednisolone Sodium Succinate for 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:	GHS

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: WARNING.

GHS Class:
Skin Irritation. Category 2.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Causes skin irritation.
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.
IF ON SKIN: Wash with plenty of water.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation occurs: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
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.
Signs/Symptoms:	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Therapeutic side effects may include: Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, muscle weakness, steroid myopathy, loss of muscle mass, severe arthalgia, peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, impaired wound healing, thin fragile skin, petechiae and ecchymosis, increased cranial pressure with papilledema (usually after treatment, convulsions, vertigo, development of Cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness, posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos, negative nitrogen balance due to protein catabolism, anaphylactic reaction, hyper/hypopigmentation, subcutaneous and cutaneous atrophy, sterile abscess, urticaria, nausea and vomiting, cardiac arrhythmias, hypotension, or hypertension. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	Overexposure to corticosteroids may increase susceptibility to infection including reactivation of latent tuberculosis and enhancement of secondary eye infection due to fungi or viruses, or mask some signs of infection. Recent immunization procedures may result in a lack of antibody response and neurological disorders. Hypersensitivity to this material may result. Corticosteroids exhibit enhanced effects on persons with hypothyroidism or cirrhosis.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Methylprednisolone Sodium Succinate	2375-03-3	40 mg, 125 mg, and 1 gm vials	
Monobasic Sodium Phosphate Anhydrous	7558-80-7	See package insert	
Dibasic Sodium Phosphate Dried	7668-79-4	See package insert	
Lactose	63-42-3	See package insert	
Benzyl Alcohol	100-51-6	See package insert	

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].
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:	White to off-white.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Very soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.

pH:	7 - 8
Molecular Formula:	Mixture
Molecular Weight:	496.53
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:	No conditions contributing to instability are known to exist for normal handling of this product.
Special Decomposition Products:	Thermal decomposition or burning may produce noxious products including carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 11 : TOXICOLOGICAL INFORMATION

Methylprednisolone Sodium Succinate :

Acute Toxicity:

LD50 IV Rat: 718 mg/kg
LD50 IP Female Rat: 512 mg/kg
LD50 IP Male Rat: 1012 mg/kg
LD50 IV Mouse: 953 mg/kg
LD50 IP Mouse: 902 mg/kg

Methylprednisolone Sodium Succinate :

RTECS Number: TU4154060

Ingestion:

Oral - Mouse LD50 : >5 gm/kg [Lungs, Thorax, or Respiration - Respiratory stimulation]
Oral - Rat LD50 : >5 gm/kg [Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Hair]

Other Toxicological Information:

Intravenous. - Rat LD50 : 640 mg/kg [Sense Organs and Special Senses (Eye) - lacrimation Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia]
Intravenous. - Mouse LD50 : 750 mg/kg [Behavioral - changes in motor activity (specific assay) Vascular - regional or general arteriolar or venous dilation Lungs, Thorax, or Respiration - respiratory depression]
Intravenous. - Rat TDLo : 50 mg/kg [Kidney, Ureter, Bladder - other changes in urine composition]
Intravenous. - Rat TDLo : 280 mg/kg/14D-I [Endocrine - changes in adrenal weight Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Subcutaneous - Mouse LD50 : 860 mg/kg [Vascular - regional or general arteriolar or venous dilation Lungs, Thorax, or Respiration - chronic pulmonary edema]
Subcutaneous - Rat TDLo : 2.4 mg/kg/24H [Blood - changes in other cell count (unspecified)]
Subcutaneous - Rat LD50 : 750 mg/kg [Behavioral - stiffness Vascular - regional or general arteriolar or venous dilation Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Mouse TDLo : 400 mg/kg/5D-I [Immunological Including Allergic - decrease in cellular immune response]
Subcutaneous - Mouse TDLo : 320 mg/kg/10D-I [Immunological Including Allergic - decrease in cellular immune response Immunological Including Allergic - decrease in humoral immune response]
Subcutaneous - Rat TDLo : 48 mg/kg/2D-C [Endocrine - changes in thymus weight Blood - changes in spleen Blood - changes in other cell count (unspecified)]
Subcutaneous - Rat TDLo : 288 mg/kg/4D-C [Liver - other changes Endocrine - changes in thymus weight Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Subcutaneous - Rat TDLo : 100 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Rat TDLo : 400 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse LD50 : 880 mg/kg [Behavioral - changes in motor activity (specific assay) Vascular - regional or general arteriolar or venous dilation Lungs, Thorax, or Respiration - respiratory stimulation]
Intraperitoneal. - Rat LD50 : 640 mg/kg [Vascular - regional or general arteriolar or venous dilation Lungs, Thorax, or Respiration - chronic pulmonary edema Lungs, Thorax, or Respiration - respiratory stimulation]
Intraperitoneal. - Rat TDLo : 300 mg/kg/30D-C [Kidney, Ureter, Bladder - other changes in urine composition Endocrine - changes in spleen weight Blood - changes in erythrocyte (RBC) count]
Intraperitoneal. - Rat TDLo : 455 mg/kg/13W-C [Kidney, Ureter, Bladder - other changes in urine composition Endocrine - changes in spleen weight Blood - changes in leukocyte (WBC) count]
Intraperitoneal. - Rat TDLo : 182 mg/kg/26W-C [Endocrine - changes in spleen weight Blood - changes in leukocyte (WBC) count Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Rat TDLo : 240 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Effects on Newborn - stillbirth]
Intraperitoneal. - Rat TDLo : 80 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth)]
Intraperitoneal. - Rat TDLo : 690 mg/kg [Reproductive - Fertility - other measures of fertility Reproductive -

Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo : 2070 mg/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Mouse TDLo : 300 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]

Monobasic Sodium Phosphate Anhydrous :

RTECS Number: WA1900000

Eye: Eye - Rabbit Standard Draize test.: 150 mg [mild]

Ingestion: Oral - Rat LD50 : 8290 mg/kg [Details of toxic effects not reported other than lethal dose value]

Lactose :

RTECS Number: OD9625000

Ingestion: Oral - Rat LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Subcutaneous - Rat LD50 : >5 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo : 1000 gm/kg/29w-C [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Tumorigenic - tumors at site of application]
Intraperitoneal. - Rat LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value]

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]

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

EINECS Number:	219-156-8
Monobasic Sodium Phosphate Anhydrous :	
TSCA Inventory Status:	Listed
EINECS Number:	231-449-2
Canada DSL:	Listed
Lactose :	
TSCA Inventory Status:	Listed
EINECS Number:	200-559-2
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)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
SDS Format:	GHS
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