PHARMACIA & UPJOHN MSDS

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: SOLU-MEDROL® Sterile Powder

USE: Human drug indicated in the treatment of endocrine, rheumatic, collagen, skin, allergic, eye, respiratory, blood, neoplastic, edematous and gastrointestinal disorders.

MANUFACTURER/SUPPLIER:

PHARMACIA & UPJOHN
7171 PORTAGE RD.
KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS:

(616) 833-5122 (24 Hours)
(616) 833-7555 (8:00 AM - 4:30 PM)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1

COMMON NAME: Methylprednisolone Sodium Succinate.
CHEMICAL NAME: Pregna-1,4-diene-3,20-dione, 21-(3-carboxy-1-oxopropoxy)-11,17-dihydroxy- 6-methyl-, monosodium salt, (6,11)-
% BY WEIGHT: 67% to 87%
CAS NUMBER: 2375-03-3

EXPOSURE LIMIT(S):
PHARMACIA & UPJOHN EXPOSURE LIMIT TWA: 4 mcg/m3
SKIN NOTATION: Yes.

INGREDIENT 2

COMMON NAME: Sodium Phosphate, Dibasic (Anhydrous).
% BY WEIGHT: 12% to 30%
CAS NUMBER: 7558-79-4

EXPOSURE LIMIT(S): Not established.

INGREDIENT 3

COMMON NAME: Sodium Phosphate, Monobasic.
% BY WEIGHT: 1% to 3%
CAS NUMBER: 7558-80-7

EXPOSURE LIMIT(S): Not established.

INGREDIENT 4

COMMON NAME: Lactose.
% BY WEIGHT: 0% to 3.2%
CAS NUMBER: 63-42-3

EXPOSURE LIMIT(S): Not established.
EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion and inhalation.

EFFECTS OF OVEREXPOSURE: There are no adverse effects of overexposure anticipated during normal handling of vials of this product. The active ingredient in SOLU-MEDROL is methylprednisolone sodium succinate, which belongs to a class of steroids called glucocorticoids. Glucocorticoids affect carbohydrate, protein and fat metabolism; functions of the cardiovascular system, kidney, skeletal muscle, nervous system and other organs and tissues; and may modify the body's immune responses to diverse stimuli. Chronic overexposure to glucocorticoids may produce pituitary-adrenal suppression, Cushing's syndrome (redistribution of body fat to face causing "moon face"), increased susceptibility to infections (suppression of inflammatory response), osteoporosis, cataracts, glaucoma with possible damage to optic nerve, mental symptoms, hyperglycemia and glycosuria, muscular weakness and fatigue, acne, menstrual disorders and peptic ulcers. Naturally occurring glucocorticoids (such as hydrocortisone and cortisone), in average and large doses, can cause elevation of blood pressure, salt and water retention, and increased potassium excretion. These effects are less likely to occur with methylprednisolone sodium succinate except in large doses. All corticosteroids increase calcium excretion.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Overexposure to corticosteroids may increase susceptibility to infection (including reactivation of latent tuberculosis and enhancement of secondary eye infections 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.

4. FIRST AID MEASURES

EYES: Flush with water for 15 minutes. Hold eyelids open to assure complete contact with water.

SKIN: Wash with soap and water. Remove contaminated clothing.

INHALATION: Remove from exposure.

INGESTION: Contact a physician or poison control center.

NOTES TO PHYSICIAN: Methylprednisolone sodium succinate has a plasma half-life of 2.3 to 4.0 hours in normal subjects. The duration of pharmacological activity, however, is 18 to 36 hours.

5. FIRE FIGHTING MEASURES

FLASH POINT: Nonflammable.

LOWER EXPLOSION LIMIT (LEL): Not applicable.

UPPER EXPLOSION LIMIT (UEL): Not applicable.

EXTINGUISHING MEDIA: Water, carbon dioxide or dry chemical.

FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full-body protective equipment.

UNUSUAL FIRE OR EXPLOSION HAZARDS: As with all finely divided organic powders, it is advisable to eliminate explosion hazards by methods such as grounding mechanical equipment in contact with the material to prevent the buildup of static electricity, inerting the atmosphere or controlling dust levels.

HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Remove ignition sources; control the generation of dust/vapors; provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep out of drains; prevent entry to surface water, groundwater and soil. Vacuum (with HEPA-filtered and explosion-proof equipment) or scoop spilled material and place in container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothes before reuse. Store in a cool, dry place and protect from light. Keep out of the reach of children. The incidence of adverse effects from corticosteroid treatment increases with prolonged exposures over periods of weeks or months. Store undiluted product at controlled room temperature of 15° to 30°C (59° to 86°F). Use solutions within 48 hours after diluting.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required.

VENTILATION: Local exhaust.

PROTECTIVE GLOVES: Rubber.

EYE PROTECTION: Safety glasses with side shields.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: White powder in standard vials or in compartmentalized vials containing powder and diluent (ACT-O-VIAL).

SOLUBILITY IN SOLVENTS: Soluble in alcohol. Insoluble in chloroform.

SOLUBILITY IN WATER: Freely soluble.

10. STABILITY AND REACTIVITY

STABILITY: Stable.

PHYSICAL CONDITIONS TO AVOID: None.

INCOMPATIBILITY WITH OTHER MATERIALS: None. **HAZARDOUS DECOMPOSITION PRODUCTS:** None.

HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES:

EYE IRRITATION (RABBIT): No irritation (methylprednisolone acetate intermediate).
SKIN IRRITATION (RABBIT): No irritation (methylprednisolone acetate intermediate).
SENSITIZATION: Anaphylactoid reactions have been reported.
INTRAVENOUS LD50 (RAT): 718 mg/kg
INTRAVENOUS LD50 (MOUSE): 953 mg/kg
ORAL LD50 (RAT): >5 g/kg
INTRAPERITONEAL LD50 (RAT): 512 mg/kg (for females; 1,012 mg/kg for males). Females are more susceptible to toxicity by this route.
INTRAPERITONEAL LD50 (MOUSE): 902 mg/kg

OTHER STUDIES:

GENOTOXICITY: Mutagenicity: negative in DNA damage/alkaline elution assay.

REPRODUCTION/FERTILITY: Subcutaneous administration of methylprednisolone sodium succinate to rats at 40 mg/kg/day resulted in adverse reproductive effects as indicated by decreases in the number of implants, fetal resorptions and death, and decreases in fetal body weight.

TERATOGENICITY: Subcutaneous administration of methylprednisolone sodium succinate to rats at 40 mg/kg/day resulted in increases in fetal malformations. Corticosteroids

are generally teratogenic in laboratory animals when administered systemically, but there are no well-controlled studies in women. The safety of their use in pregnant women has not been absolutely established.

CARCINOGENICITY: Ingredients are not listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE:

MOBILITY: This material is very soluble in water. Therefore, it is expected to be mobile and migrate to the aquatic compartment. As a solid with assumably no measurable vapor pressure, it is not expected to enter the air.

PERSISTENCE/DEGRADABILITY: Studies on steroid degradation by soil microorganisms indicate that microbes similar to those found in activated sludge are capable of biodegrading steroids completely.

BIOACCUMULATIVE POTENTIAL: This material is highly soluble in water and poorly soluble in non-polar mediums and as such would be expected to have a low bioaccumulative potential.

ABIOTIC POTENTIAL: In general, it has been shown that microbes similar to those found in activated sludge are capable of biodegrading steroids and are not inhibited by their presence.

ECOTOXICITY: No information found.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable international, national, state, and/or local waste disposal regulations.

14. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

15. OTHER INFORMATION

REVIEWED BY: Environment and Safety.

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16. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.