

**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION****COMMON NAME:** SOLU-CORTEF® Sterile Powder**USE:** Human drug indicated in the treatment of endocrine, rheumatic, collagen, nervous, skin, allergic, eye, respiratory, blood, neoplastic, edematous and gastrointestinal disorders.**MANUFACTURER/SUPPLIER:**THE UPJOHN COMPANY  
7171 PORTAGE RD.

KALAMAZOO, MI 49001-0199

**TELEPHONE NUMBERS:**

(616) 323-5122 (24 Hours)

(616) 323-7555 (8:00 AM - 4:30 PM)

**2. COMPOSITION/INFORMATION ON INGREDIENTS****INGREDIENT 1****COMMON NAME:** Hydrocortisone Sodium Succinate.**CHEMICAL NAME:** Pregn-4-ene-3,20-dione,  
21-(3-carboxy-1-oxoproxy)-11,17-dihydroxy-,  
monosodium salt, (11 $\beta$ )-**% BY WEIGHT:** 93%**CAS NUMBER:** 125-04-2**EXPOSURE LIMIT(S):**UPJOHN EXPOSURE LIMIT-TWA: 20  $\mu\text{g}/\text{m}^3$ **SKIN NOTATION:** Yes.**INGREDIENT 2****COMMON NAME:** Sodium Phosphate, Dibasic  
(Anhydrous).**% BY WEIGHT:** 6.4%**CAS NUMBER:** 7558-79-4**EXPOSURE LIMIT(S):** Not established.**INGREDIENT 3****COMMON NAME:** Non-hazardous Ingredient(s).**% BY WEIGHT:** <1%**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 this product. The active ingredient in SOLU-CORTEF is hydrocortisone sodium succinate, which belongs to the corticosteroid class of steroids. Corticosteroids affect carbohydrate, protein and fat metabolism; electrolyte and water balance; 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 corticosteroids may produce pituitary-adrenal suppression, Cushing's syndrome (redistribution of body fat to face, back of neck and trunk), increased susceptibility to infections (suppression of inflammatory response), impaired wound healing, osteoporosis, cataracts, glaucoma with possible damage to optic nerve, insomnia, mood swings, personality changes, hyperglycemia and glycosuria, muscular weakness and fatigue, acne, menstrual irregularities,**3. HAZARDS IDENTIFICATION, Con't**

and peptic ulcers. Hydrocortisone sodium succinate can cause elevation of blood pressure, electrolyte imbalances due to sodium/fluid retention and increase potassium and 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.**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. Keep out of reach of children. The incidence of adverse effects from corticosteroid treatment increases with prolonged exposures over

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periods of weeks or months. Store undiluted product at controlled room temperature 15° to 30°C (59° to 86°F). Store solution at controlled room temperature 15° to 30°C (59° to 86°F) and protect from light and use solution only if it is clear. Unused solution should be discarded after 3 days.

**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 to off-white amorphous powder in compartmentalized vials containing powder and diluent (ACT-O-VIAL®).

**MELTING POINT:** 169° to 171.2°C (336° to 340°F)

**ODOR:** Odorless.

**SOLUBILITY IN SOLVENTS:** Very soluble in ethanol and methanol; slightly soluble in acetone; practically 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):** Nonirritating.

**SKIN IRRITATION (RABBIT):** Negative (hydrocortisone sodium succinate).

**ORAL LD<sub>50</sub> (RAT):** 17 g/kg (dibasic sodium phosphate).

**INTRAPERITONEAL LD<sub>50</sub> (RAT):** 132 mg/kg (hydrocortisone sodium succinate).

**INTRAPERITONEAL LD<sub>50</sub> (MOUSE):**

1,050 mg/kg (hydrocortisone sodium succinate).

**OTHER STUDIES:**

**GENOTOXICITY:** Mutagenicity: No information found.

**TERATOGENICITY:** 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:** Ingredient(s) are not listed as carcinogenic 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 and a high melting point, it is not expected to enter the air.

**PERSISTENCE/DEGRADABILITY:** Studies on steroid degradation by soil microorganisms indicate that these compounds are readily biodegraded. Other studies have shown 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:** Health and Safety Regulatory Affairs.

**DISCLAIMER:** The MSDS information is believed to be correct but should only be used as a guide. The Upjohn Company disclaims any express or implied warranty as to the accuracy of the MSDS information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the information.

**16. LABELING**

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

NDC 0009-0825-01  
NDC 0009-0900-13  
NDC 0009-0900-15  
NDC 0009-0909-08

NDC 0009-0909-09  
NDC 0009-0912-05  
NDC 0009-0920-03