MATERIAL SAFETY DATA SHEET

Product Name: Hydrocortisone Sodium Succinate for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Hydrocortisone Sodium Succinate for Injection, USP

Synonyms
pregn-4-ene-3,20-dione,21-(3-carboxy-1-oxoproxy)-11,17-dihydroxy-,
monosodium salt, (11β)-

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Hydrocortisone Sodium Succinate

Chemical Formula
C₂₅H₃₃O₈ • Na

Preparation
Sodium hydroxide may be added for pH adjustment.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Sodium Succinate</td>
<td>91</td>
<td>125-04-2</td>
<td>GM9015000</td>
</tr>
<tr>
<td>Sodium Phosphate, Dibasic</td>
<td>9</td>
<td>7558-79-4</td>
<td>WC4500000</td>
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<tr>
<td>Monobasic Sodium Phosphate</td>
<td>&lt;1</td>
<td>7558-80-7</td>
<td>WA1900000</td>
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</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Sodium Succinate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Monobasic Sodium Phosphate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Hydrocortisone Sodium Succinate for Injection, USP is a powder for reconstitution intended for intravenous or intramuscular administration. It contains hydrocortisone sodium succinate, an anti-inflammatory and immunosuppressive adrenalcorticoid. Clinically, it is used to treat endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, inflammatory states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, and other disorders. In the workplace, this material should be considered potentially irritating to the eyes. Based on clinical use, possible target organs include the gastrointestinal, immune, central nervous, and endocrine systems; skin and eyes.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
**Product Name:** Hydrocortisone Sodium Succinate for Injection, USP

**Signs and Symptoms**
None known from workplace exposures. In clinical use, adverse effects include fluid and electrolyte disturbances, musculoskeletal weakness and myopathy, gastrointestinal disturbances (peptic ulcers), dermatologic reactions (allergic dermatitis), endocrine disturbances (adrenocortical suppression, suppression of growth in children), neurologic disturbances (vertigo, headache, psychosis), and ophthalmic disturbances (glaucoma, cataracts). Prolonged use of hydrocortisone may produce immune suppression, increasing the susceptibility to and masking the symptoms of infections.

**Medical Conditions Aggravated by Exposure**
Pre-existing hypersensitivity to hydrocortisone sodium succinate or the product ingredients; pre-existing systemic fungal infections, glaucoma, cataracts; endocrine or immune system disorders; pregnancy.

### 4. FIRST AID MEASURES

**Eye contact**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin contact**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

### 5. FIRE FIGHTING MEASURES

**Flammability**
None anticipated for this product. However, many organic powders will combust at high temperatures.

**Fire & Explosion Hazard**
None anticipated for this product. Minimize the generation of dusty environments.

**Extinguishing media**
As with any fire, use extinguishing media appropriate for primary cause of fire.

**Special Fire Fighting Procedures**
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal**
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using techniques that minimize the creation of airborne dusts. If the spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
7. HANDLING AND STORAGE

Handling  No special handling required under conditions of normal product use.

Storage  No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions  No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Phosphate, Dibasic</td>
<td>Not Applicable</td>
<td>mg/m3 ppm µg/m3</td>
</tr>
<tr>
<td>Monobasic Sodium Phosphate</td>
<td>Not Applicable</td>
<td>mg/m3 ppm µg/m3</td>
</tr>
<tr>
<td>Hydrocortisone Sodium Succinate</td>
<td>Hospira EEL</td>
<td>N/A N/A 100</td>
</tr>
</tbody>
</table>

Respiratory protection  Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection  If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection  Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls  Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance/Physical State</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>White, or nearly white</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>7 to 8</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Hydrocortisone Sodium Succinate for Injection, USP

Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: It is very soluble in water and in alcohol, very slightly soluble in acetone and insoluble in chloroform.
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.
Chemical Stability Stable under standard use and storage conditions.
Hazardous Reactions Not determined.
Conditions to avoid Not determined.
Incompatibilities Not determined.
Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and oxides of sodium (NaOx).
Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Sodium Succinate</td>
<td>100%</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>1320</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1050</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Sodium Phosphate, Dibasic</td>
<td>100%</td>
<td>LD50</td>
<td>Oral</td>
<td>17000</td>
<td>mg/kg</td>
<td>Rat</td>
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</table>

Aspiration Hazard None anticipated from normal handling of this product.
Dermal Irritation/Corrosion None anticipated from normal handling of this product. Dibasic sodium phosphate was mildly irritating in studies in animals.
Ocular Irritation/Corrosion None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation. Dibasic sodium phosphate was mildly irritating in studies in animals.
Dermal or Respiratory Sensitization None anticipated from normal handling of this product. Occasionally, dermatological reactions have been reported during the clinical use of this product.
Product Name: Hydrocortisone Sodium Succinate for Injection, USP

Reproductive Effects  Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women.

Mutagenicity  Studies have not been conducted in animals to determine whether corticosteroids have a potential for mutagenesis.

Carcinogenicity  Studies have not been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis.

Target Organ Effects  Based on clinical use, possible target organs include the gastrointestinal, immune, central nervous, and endocrine systems; skin and eyes.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity  Not determined for product.

Persistence/Biodegradability  Not determined for product.

Bioaccumulation  Not determined for product.

Mobility in Soil  Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal  All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal  Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:  Not regulated

IMDG STATUS:  Not regulated

ICAO/IATA STATUS:  Not regulated

Transport Comments:  None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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Product Name: Hydrocortisone Sodium Succinate for Injection, USP

RCRA Status Not Listed
U.S. OSHA Classification Target Organ Toxin
Possible Irritant

GHS Classification
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable
Hazard Category Not Applicable
Signal Word Not Applicable
Symbol Not Applicable
Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable
Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Hydrocortisone Sodium Succinate.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases:

S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
Product Name: Hydrocortisone Sodium Succinate for Injection, USP

RCRA: US EPA, Resource Conservation and Recovery Act
RTECS: Registry of Toxic Effects of Chemical Substances
SARA: Superfund Amendments and Reauthorization Act
STEL: 15-minute Short Term Exposure Limit
TSCA: Toxic Substance Control Act
TWA: 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 08/29/2011
Obsolete Date: 10/21/2008

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