1. PRODUCT IDENTIFICATION

Product Name: Dexamethasone Sodium Phosphate Injection
Product Use: Antinflammatory or Immunosuppressive Agent
Manufacturer: Teva Parenteral Medicines, Inc.
Address: 11 Hughes
Irvine, CA  92618-1902
Chemtrec Emergency No.: 1-800-424-9300 (United States)
1-202-483-7617 (International Collect)
Business Phone: 1-800-729-9991
Website Address: http://www.newsicor.com
Common Names: Hexadrol® Betnelan phosphate
Chemical Name: 9-fluoro-11β, 17-dihydroxy-16α-methyl—21-(phosphonoxy) pregna-1,4-
diene-3,20-dione disodium salt
Chemical Formula: C_{22}H_{28}FNa_2O_8P
Chemical Family: Glucocorticoid
How Supplied: 10 mg/mL in 10 mL
4 mg/mL in 2 mL and 5 mL vial
Date of Preparation: December 4, 2005

2. COMPOSITION AND INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS#</th>
<th>EXPOSURE LIMITS IN AIR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wt%</td>
<td>ACGIH TLV</td>
</tr>
<tr>
<td>Dexamethasone Sodium Phosphate, USP</td>
<td>2392-39-4</td>
<td>1</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>68-04-0</td>
<td>1</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>1</td>
</tr>
<tr>
<td>Sodium Metabisulfite</td>
<td>7681-57-4</td>
<td>1</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Balance</td>
</tr>
</tbody>
</table>

NE - Not Established  C - Ceiling Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 format
CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

3. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:** Material is a colorless to pale yellow liquid. May cause allergic skin reactions. May be harmful to the fetus. Overexposure may cause damage to the adrenal glands and immune systems. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling. Can emit hydrogen fluoride upon combustion.
3. HAZARD IDENTIFICATION cont…

Symptoms of Overexposure by Route of Exposure: This material is intended for injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact may cause mild irritation. Effects may include stinging, watering, and redness of the eyes and redness, itching, and a burning sensation on the skin. May cause an allergic skin reaction.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, it is considered slightly toxic based on animal data. Symptoms similar to those identified under injection may occur. Ingestion may also cause allergic reaction due to the bisulfite present in the solution.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including Cushing’s syndrome, water retention, electrolyte imbalance, hypertension, hyperglycemia, myopathy and suppression of adrenal gland secretions may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as Cushing’s syndrome (fat redistribution, bruising, acne and hirsuitism), water retention, electrolyte imbalance (e.g., edema, low potassium), high blood pressure, hyperglycemia (high blood glucose) and suppression of adrenal gland secretions may occur.

Cancer: No long-term carcinogenicity studies were identified.

Chronic: Overexposure may cause effects on the adrenal glands and immune system (see Section 11).

Other: This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissues. Benzyl alcohol has been reported to be associated with fatal “gaping syndrome” in premature infants.

Persons who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chicken pox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include skin, kidney, nervous system and hearing disorders.

4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.
4. FIRST-AID MEASURES cont…

**Eye Exposure:** If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

**Inhalation:** If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

**Ingestion:** If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

**Note to Physicians:** Systemic absorption of this material can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment. Clinical effects from withdrawal can range from symptoms of fever, muscle pain, joint pain and malaise to life-threatening cardiovascular collapse. Manifestations of Cushing syndrome, hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of corticosteroids while on therapy.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

5. FIRE-FIGHTING MEASURES

**Flash Point:** Non-flammable  
**Autoignition Temperature:** Not applicable  
**Flammable Limits (in air by volume, %):** Lower: Not applicable  
Upper: Not applicable

**Fire Extinguishing Equipment:** Use extinguishing agent suitable for type of surrounding fire.

- Water Spray: OK  
- Carbon Dioxide: OK  
- Halon: OK  
- Foam: OK  
- Dry Chemical: OK  
- Other: Any "ABC" Class

**Unusual Fire and Explosion Hazards:** No unusual fire or explosion hazards are expected.

- **Explosion Sensitivity to Mechanical Impact:** Not sensitive.
- **Explosion Sensitivity to Static Discharge:** Not sensitive.

**Special Fire Fighting Procedures:** For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.
5. FIRE-FIGHTING MEASURES cont…

NFPA HAZARD CLASS:  Health:  2 (Moderate)
                      Flammability:  0 ( Least)
                      Reactivity:  0 ( Least)

6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Sensitive to heat. Protect from freezing. Store at controlled room temperatures 15-30°C (59-86°F).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.
8. EXPOSURE CONTROLS - PERSONAL PROTECTION


Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer’s respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative Vapor Density (air = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity (water = 1)</td>
<td>~1</td>
</tr>
<tr>
<td>Solubility in Water:</td>
<td>Soluble</td>
</tr>
<tr>
<td>Vapor Pressure, mm Hg @ 25°C.</td>
<td>Not available</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Appearance and Color:</td>
<td>Clear, colorless to pale yellow liquid</td>
</tr>
<tr>
<td>Evaporation Rate (n-BuAc=1):</td>
<td>Approx. 1</td>
</tr>
<tr>
<td>Melting/Freezing Point:</td>
<td>~ 0°C</td>
</tr>
<tr>
<td>Boiling Point:</td>
<td>~100°C</td>
</tr>
<tr>
<td>pH</td>
<td>7.0-8.5</td>
</tr>
</tbody>
</table>

10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility. Keep away from oxidizing agents, strong acids and caustics.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Heat may cause product to decompose, destroying the product or producing toxic fumes.
11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Dexamethasone Sodium Phosphate the active ingredient

Oral LD50 (mouse) = 1.8 g/kg  IV LD50 (mouse) = 932 mg/kg
IP LD50 (mouse) = 550 mg/kg

Suspected Cancer Agent: No long-term animal studies were identified. It is not listed as carcinogenic by NTP, IARC or OSHA.

Irritancy of Product: This product is expected to be mildly irritating to eyes and skin.

Sensitization to the Product: Dexamethasone is used often to treat inflammation / rashes of the skin. Occasionally, it may actually cause an allergic response if repeatedly contacting the skin.

Target Organs: Overexposure may cause effects on the adrenal glands (suppression of secretions) and immune system (increased susceptibility to infection).

Reproductive Toxicity Information: Listed below is information concerning the effects of Dexamethasone Sodium Phosphate on human and animal reproductive systems.

Mutagenicity: Dexamethasone has been reported to cause genetic damage in several in vitro short-term screening tests.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Dexamethasone and other glucocorticosteroids have been reported to be teratogenic in several laboratory animals. However, there apparently are no reports of reproductive or developmental toxicity in humans.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Dexamethasone Sodium Phosphate on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Dexamethasone Sodium Phosphate on plants or animals in the aquatic environment.
13. DISPOSAL CONSIDERATIONS
Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA “listed” or “characteristic” hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.
U.S. EPA Waste Number: None

14. TRANSPORTATION INFORMATION
This Material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation
Proper Shipping Name: Not applicable
Hazard Class Number and Description: Not applicable
UN Identification Number: Not applicable
Packing Group: Not applicable
DOT Label(s) Required: Not applicable
MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)
Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

15. REGULATORY INFORMATION

U.S. REGULATIONS
U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.
U.S. SARA Threshold Planning Quantity: Not applicable
U.S. CERCLA Reportable Quantities (RQ): Not applicable
U.S. TSCA Inventory Status: Dexamethasone Sodium Phosphate is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does not contain chemicals known to the State of California to cause cancer or reproductive effects.
Other U.S. Federal Regulations: Based on this product’s use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable.
15. REGULATORY INFORMATION cont…

CANADIAN REGULATIONS

Canadian DSL/NDSL Status: Dexamethasone Sodium Phosphate is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): May cause allergic skin reactions. May be harmful to the fetus. Overexposure may cause damage to the adrenal glands and immune systems. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling. Avoid accidental injection. Do not eat, drink or smoke when handling. Clean up spills promptly.

16. OTHER INFORMATION

Issue Date: 12/02/05
Previous Issue Date: 7/14/04

The information in this document is believed to be correct as of the date issued. HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THIS INFORMATION, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE. This information and product are furnished on the condition that the person receiving them shall make his own determination as to the suitability of the product for his particular purpose and on the condition that he assume the risk of his use thereof.