



# MATERIAL SAFETY DATA SHEET

## Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP

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glucocorticoids used as anti-inflammatory or immunosuppressant agents. The product is used to treat inflammatory conditions of joints, and is typically administered via intramuscular injection. See section 11 for specific toxicological information.

**Route(s) of Entry:** Absorption may occur through skin or eyes. Exposure due to inhalation or ingestion is unlikely.

**Signs and Symptoms of Exposure:** Exposure may cause skin, eye or respiratory tract irritation and sensitization. Corticosteroid exposure may lead to tuberculosis or tuberculin reactivity. Acne and skin irritation are symptoms of exposure to betamethasone acetate. Prolonged exposure may cause suppression of suprarenal gland secretion, Cushing syndrome, water retention, electrolyte imbalance and hyperglycemia. Potential for exposure is reduced in this form as a finished pharmaceutical product under normal conditions of use.

**Target Organ(s):** Skin, kidneys, respiratory and gastrointestinal systems.

**Listed Carcinogenicity:** NTP: No IARC: No OSHA: No

**Medical Conditions Aggravated by Exposure:** Non-specific ulcerative colitis, diverticulitis, ulcers, renal insufficiencies, hypertension, osteoporosis/myasthenia or immunization procedures. Persons sensitive to other corticosteroids may be sensitive to this material as well.

### SECTION 4: FIRST AID MEASURES

- **Eyes:** Flush eyes with copious amount of water for not less than 15 minutes. Seek medical treatment from a physician.
- **Skin:** Remove contaminated clothing. Flush affected area with mild soap and water for not less than 15 minutes. Seek medical attention if irritation or other symptoms develop.
- **Ingestion:** If ingestion occurs, seek medical attention immediately.
- **Inhalation:** If difficulty breathing, seek medical attention immediately. If necessary, provide artificial respiration.

**Note(s) to Physician:** Overdose should be treated symptomatically. Additional information is available in the package insert.

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### SECTION 5: FIRE AND EXPLOSION HAZARD DATA

- **Flash Point:** Not Applicable (N/A) Method: N/A
- **Lower Explosion Limit (LEL):** N/A
- **Upper Explosion Limit (UEL):** N/A
- **Extinguishing Media:** Multi-purpose or water, if appropriate for situation.
- **Fire Fighting Procedures:** Evacuate personnel. Fire fighters must wear protective clothing and self-contained breathing apparatus.
- **Unusual Fire/Explosion Hazards:** None.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

**Spill Procedures:** Wear appropriate personal protective equipment and avoid direct contact with material. Contain the spill to prevent additional exposure by personnel and contact with drains. Absorb with suitable material. Dispose of all contaminated material in appropriate container in accordance with local, state and federal regulations for waste disposal.

**Release to Environment:** Wear appropriate personal protective equipment and avoid direct contact with material. Prevent contact with drains, sewers and streams. Contact local authorities if release occurs into drains, sewers, streams or other public areas. Absorb with suitable material. Dispose of all contaminated material in appropriate container in accordance with local, state and federal regulations for waste disposal.

### SECTION 7: HANDLING AND STORAGE

**Handling Procedures:** Wear appropriate personal protective equipment in cases where exposure may occur, including gloves, lab coat, and eye protection. Additional protective equipment may be required, including the use of respiratory protection and/or additional protective clothing.

**Storage Procedures:** Store at 20-25°C (68-77°F); see USP controlled room temperature. Protect from exposure to light and avoid excessive heat.

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### SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

- **Skin Protection:** Use latex or nitrile gloves. Wash hands following use.
- **Eye Protection:** Use safety glasses or goggles.
- **Respiratory Protection:** Under normal product conditions, respiratory protection should not be required if used in an area with adequate ventilation. Large spills or generation of dust may require the use of approved air-purifying respirators or self-contained breathing apparatus (SCBA).
- **Other Protective Clothing or Equipment:** Lab coat.

### SECTION 9: PHYSICAL / CHEMICAL CHARACTERISTICS

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP is provided as a matrix of white suspended powder in a clear, colorless liquid.

- **Physical State:** Aqueous Suspension
- **Appearance/Odor:** Clear, colorless, no odor
- **Boiling Point:** Approximate to water
- **Vapor Pressure:** Approximate to water
- **Vapor Density:** Approximate to water
- **Solubility (Water):** Acetate derivative is insoluble, Phosphate derivative is soluble
- **Specific Gravity:** Approximate to water
- **Melting Point:** Not Applicable
- **Evaporation Rate:** Approximate to water
- **pH:** 6.8 – 7.2

### SECTION 10: STABILITY AND REACTIVITY

- **Chemical Stability:** Stable
- **Incompatibility:** Oxidizers, Strong Acids and Bases
- **Hazardous Decomposition Products:** Decomposition products of this material may include potentially hazardous byproducts of carbon monoxide, carbon dioxide, phosphorous oxides and hydrogen fluoride.
- **Hazardous Polymerization:** Will not occur.
- **Conditions to Avoid:** Protect from light and excess heat.

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### SECTION 11: TOXICOLOGICAL INFORMATION

Both active ingredients have been identified as potential irritants to the skin, eyes, respiratory and gastrointestinal tracts. Data for the individual active ingredients are shown below.

Betamethasone Sodium Phosphate, RTECS # TU4056500:

LD<sub>50</sub> oral, rat = 1877 mg/kg  
LD<sub>50</sub> intravenous, rat = 1276 mg/kg  
LD<sub>50</sub> intramuscular, rat = 1291 mg/kg

Betamethasone sodium phosphate has been identified as having possible teratogenic effects in rats and mice. Somnolence, respiratory depression and body temperature decrease have been observed in toxicology studies.

Betamethasone Acetate

Betamethasone acetate has been identified as showing limited evidence of a carcinogenic effect and possible teratogenic effects. Specific toxicology data not found.

### SECTION 12: ECOLOGICAL INFORMATION

Information on the environmental impact of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP is not currently available. Under normal conditions of use, the material is not anticipated to have a significant impact on the environment. Handle in such a manner as to prevent spills or the accidental release of the material.

### SECTION 13: DISPOSAL INFORMATION

Dispose of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP in accordance with all applicable local, state and federal regulations.

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### SECTION 14: TRANSPORTATION INFORMATION

- **Department of Transportation (DOT) Hazardous Material:** No
- **IATA/ICAO Status:** Not Regulated

### SECTION 15: REGULATORY INFORMATION

- **SARA Title III Section 313:** Not Listed
- **TSCA Status:** Not Listed
- **CERCLA Status:** Not Listed
- **EPA/RCRA Status:** Not Listed
- **California Proposition 65 Status:** Not Listed

### SECTION 16: OTHER INFORMATION

The health, safety and environmental information and recommendations contained herein represent that which we believe to be accurate, complete and representative of the material(s) listed above. We believe the sources used to gather this information are reliable. However, the information contained in this MSDS is provided without warranty of any kind, expressly or implied. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability and completeness of the information for any specific use or purpose and to adopt such safety precautions that may be necessary to assure proper use of the material(s) and the health and safety of employees and customers.

**Date Prepared:** 03/26/2009

**Date Revised:** N/A