



Luitpold Pharmaceuticals

AMERICAN REGENT, INC.

**MATERIAL SAFETY DATA SHEET****Section 1: PRODUCT AND COMPANY INFORMATION**

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**PRODUCT NAME:** Dexamethasone Sodium Phosphate Injection, USP

**PRODUCT CODE (NDC):** 4 mg/mL: 0517-4901-25, 0517-4905-25, 0517-4930-25

**Section 2: HAZARDS IDENTIFICATION****EMERGENCY OVERVIEW**

|  |   |
|--|---|
| Appearance / Odor  | Clear, colorless solution with slight odor of Benzyl Alcohol.     |
| <b>WARNING!</b>  |   |
| Skin, eye and respiratory irritant                                   | Causes slight irritation of the eyes, skin and respiratory tract. |
| Toxicity to fish/aquatic organisms                                   | Product is not known to be toxic to fish.                         |
| <i>Potential Health Effects: See Section 11 for more information</i> |   |
| Likely Routes of Exposure  | Eye contact, skin contact, inhalation and ingestion.              |
| Eye  | Causes slight irritation of the eye.                              |
| Skin   | Causes slight irritation of the skin.                             |
| Inhalation   | May cause irritation of the upper and lower respiratory tract.    |
| Ingestion  | May cause irritation of the gastrointestinal tract.               |
| Skin Absorption  | Slight skin absorption.   |
| Medical Conditions Aggravated by Exposure                            | Personnel with sensitivity to any component of this product.      |
| Target Organs  | Eyes, skin, mucous membranes, upper and lower respiratory tract.  |

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**Section 2: HAZARDS IDENTIFICATION (continued)**

*Potential Environmental Effects:*  
*See Section 12 for more information*

This product is not known to be toxic to fish.

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

**Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS**

| Component                      | CAS Number | Percentage (%) by Weight |
|--------------------------------|------------|--------------------------|
| Dexamethasone Sodium Phosphate | 2392-39-4  | 0.4 percent              |
| Benzyl Alcohol                 | 100-51-6   | 1.0 percent              |
| Sodium Sulfite                 | 7757-83-7  | 0.1 percent              |
| Sodium Citrate                 | 6132-04-3  | 1.1 percent              |
| Sodium Hydroxide               | 1310-73-2  | used for pH adjustment   |
| Citric Acid                    | 77-92-9    | used for pH adjustment   |
| Water for Injection            | 7732-18-5  | 97.4 percent             |

**Section 4: FIRST AID MEASURES**

|                    |  |
|--------------------|--|
| Eye Contact        | Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.  |
| Skin Contact       | May cause irritation or contact dermatitis. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.  |
| Inhalation         | May cause irritation of respiratory tract. Anaphylactic or hypersensitivity reactions are possible with inhalation exposures. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.  |
| Ingestion          | May cause irritation, nausea, malaise, abdominal distention, peritonitis and gastric ulceration. Flush mouth out with water. Seek medical attention.   |
| Injection          | See prescribing information.   |
| Note to Physicians | Exposure to this product may result in headache, vertigo, convulsions and muscle weakness. Anaphylactic or hypersensitivity reactions are possible with inhalation exposures. Large exposures may result in hypertension and increased excretion of potassium. Allergic dermatitis may also be observed in exposed workers. See prescribing information.<br><br>This product contains Benzyl Alcohol that is used as a preservative. Benzyl Alcohol has been associated with "Gasping Syndrome" in neonates. |

**Section 5: FIRE FIGHTING MEASURES**

|  |   |
|--|---|
| Suitable Extinguishing Media   | Water spray, foam, dry chemical or Carbon Dioxide (CO <sub>2</sub> ).<br><b>Caution:</b> CO <sub>2</sub> will displace air in confined spaces and may cause an oxygen deficient atmosphere. |
| Unsuitable Extinguishing Media   | None.   |
| Hazardous Combustion Products  | When heated, Dexamethasone Sodium Phosphate solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide, halogenated compounds, phosphates and metal oxides). |
| <u>Protection for firefighters:</u> Dexamethasone Sodium Phosphate solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching. |   |

**Section 6: ACCIDENTAL RELEASE MEASURES**

|                           |   |
|---------------------------|---|
| Personnel Precautions     | Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.  |
| Environmental Precautions | This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.   |
| Methods of Containment    | Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.   |
| Methods of Clean Up       | Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water. |
| Other Information         | A spill of this material does not need to be reported to the National Response Center.  |

**Section 7: HANDLING AND STORAGE**Handling:

As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Do not mix with other drugs.

Use in a well ventilated area. Wash thoroughly after handling.

Storage:

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

| Exposure Guidelines            | OSHA PEL   | ACGIH TLV                            | OTHER |
|--------------------------------|--|--------------------------------------|-------|
| Dexamethasone Sodium Phosphate | Not listed   | Not listed                           |       |
| Sodium Citrate                 | Not listed   | Not listed                           |       |
| Benzyl Alcohol                 | Not listed   | Not listed                           |       |
| Sodium Sulfite                 | Not Listed   | Not listed                           |       |
| Citric Acid                    | Not Listed   | Not Listed                           |       |
| Sodium Hydroxide               | 2 milligrams / cubic meter - 8 hour TWA  | 2 milligrams / cubic meter - Ceiling |       |
| Water for Injection            | Not listed   | Not Listed                           |       |
| Personal Protective Equipment  | Description  |                                      |       |
| Ventilation                    | Local exhaust or general ventilation is recommended.   |                                      |       |
| Respiratory Protection         | Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with combination P-100 / organic vapor / acid gas cartridges. |                                      |       |
| Eye Protection                 | Wear ANSI approved chemical splash goggles or safety glasses.  |                                      |       |
| Skin Protection                | When administering this product to patients, wear latex or nitrile gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.                                  |                                      |       |

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

|                       |                                      |
|-----------------------|--------------------------------------|
| Color                 | Clear, colorless solution            |
| Odor / Odor Threshold | Odor of Benzyl Alcohol               |
| Physical State        | Liquid                               |
| pH                    | 7.0 to 8.5                           |
| Freezing Point        | Approximately 32 degrees Fahrenheit  |
| Boiling Point         | Approximately 212 degrees Fahrenheit |
| Flash Point           | Not applicable                       |
| Evaporation Rate      | Not applicable                       |

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| <b>Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)</b> |   |
|--|---|
| Flammability   | Nonflammable, noncombustible                        |
| Upper Flammable Limit  | Not applicable                                      |
| Lower Flammable Limit  | Not applicable                                      |
| Vapor Pressure   | Not applicable                                      |
| Vapor Density  | Not applicable                                      |
| Specific Gravity   | Approximately 1.0                                   |
| Solubility (water)   | Freely soluble in water                             |
| Partition Coefficient  | Not applicable                                      |
| Auto-ignition Temperature                                      | Not applicable                                      |
| Percent Volatile   | 1.0 percent (Benzyl Alcohol used as a preservative) |
| Volatile Organic Compounds (%)                                 | 1.0 percent (Benzyl Alcohol used as a preservative) |

| <b>Section 10: STABILITY AND REACTIVITY</b> |  |
|---|--|
| Stability                                   | Stable   |
| Conditions to Avoid                         | Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors. |
| Incompatible Materials                      | Reactive with oxidizers.   |
| Hazardous Decomposition Products            | Carbon Monoxide, Carbon Dioxide, halogenated compounds, phosphates and metal oxides may be released by thermal decomposition.  |
| Possibility of Hazardous Reactions          | Hazardous polymerization will not occur.   |

| <b>Section 11: TOXICOLOGY INFORMATION</b> |  |
|---|--|
| <b>Acute Effects</b>                      |  |
| Oral (LD <sub>50</sub> )                  | LD <sub>50</sub> : 6500 mg/kg oral - mouse                                   |
| Subcutaneous (LD <sub>50</sub> )          | No data available  |
| Intravenous (LD <sub>50</sub> )           | LD <sub>50</sub> : 794 mg/kg intravenous - mouse                             |
| Dermal (LD <sub>50</sub> )                | No data available  |
| Intraperitoneal (LD <sub>50</sub> )       | LD <sub>50</sub> : 550 mg/kg intraperitoneal - mouse                         |
| Inhalation                                | Respiratory irritation is possible.  |
| Eye Irritation                            | Eye irritation is possible.  |
| Skin Irritation                           | Skin irritation is possible.   |
| Sensitization                             | Allergic reactions may result in anaphylactic shock and allergic dermatitis. |

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**Section 11: TOXICOLOGY INFORMATION (continued)**

|                        |  |
|------------------------|--|
| <b>Chronic Effects</b> |  |
| Organ Systems          | Prolonged or repeated exposure may lead to cataracts or glaucoma.  |
| Carcinogenicity        | Dexamethasone Sodium Phosphate is not considered carcinogenic. No adequate and well controlled studies in humans have been conducted.  |
| Mutagenicity           | No adequate and well controlled studies in humans regarding the mutagenic effects of Dexamethasone Sodium Phosphate. Benzyl Alcohol used as a preservative is considered mutagenic for bacteria and yeast. Sodium Sulfite is considered mutagenic for mammalian somatic cells, bacteria and yeast. |
| Reproductive Effects   | Dexamethasone Sodium Phosphate is considered a reproductive toxin. Dexamethasone Sodium Phosphate passes into breast milk of nursing mothers.  |
| Developmental Effects  | Dexamethasone Sodium Phosphate may be teratogenic. No adequate and well controlled studies in humans. Classified as Pregnancy Category C.  |

**Section 12: ECOLOGICAL INFORMATION**

|                                |  |
|--------------------------------|--|
| Ecotoxicity                    | No data available.   |
| Persistence / Degradability    | Short term products of biodegradation are not likely. Long term degradation products may arise but are not as toxic as the product itself. |
| Bioaccumulation / Accumulation | No applicable bioaccumulation is expected in the environment.  |
| Mobility in Environment        | Appreciable volatilization is not expected into the air.   |

**Section 13: DISPOSAL CONDITIONS**

|          |   |
|----------|---|
| Disposal | Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal. |
|----------|---|

**Section 14: TRANSPORTATION INFORMATION**

| Regulatory Agency     | Shipping Description  |
|-----------------------|---|
| US DOT (ground)       | Not considered a DOT regulated material - Non hazardous for shipment. |
| Canadian TDG (ground) | See US DOT.   |
| IATA (air)            | Not considered a DOT regulated material - Non hazardous for shipment. |

**Section 15: REGULATORY INFORMATION**

|  |   |
|--|---|
| STATE RIGHT TO KNOW  | Refer to the applicable state to determine applicability.   |
| California Safe Drinking Water & Toxic Enforcement Act (Prop 65) | This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65. |
| RTECS Number   | TU4056000   |
| TSCA   | 8b Inventory - Dexamethasone Sodium Phosphate   |
| NFPA Rating  | Health - 1, Fire - 1, Reactivity - 0  |
| WHMIS (Canada)   | Not controlled  |

**Section 16: OTHER INFORMATION****Dexamethasone Sodium Phosphate Injection, USP****A. By intravenous or intramuscular injection when oral therapy is not feasible:****1. Endocrine disorders**

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance)

Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; mineralocorticoid supplementation may be necessary, particularly when synthetic analogs are used)

Preoperatively, and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful

Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected

Congenital adrenal hyperplasia

Nonsuppurative thyroiditis

Hypercalcemia associated with cancer

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**Section 16: OTHER INFORMATION (continued)**

2. *Rheumatic disorders*  
As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:  
Post-traumatic osteoarthritis  
Synovitis of osteoarthritis  
Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)  
Acute and subacute bursitis  
Epicondylitis  
Acute nonspecific tenosynovitis  
Acute gouty arthritis  
Psoriatic arthritis  
Ankylosing spondylitis
3. *Collagen diseases*  
During an exacerbation or as maintenance therapy in selected cases of:  
Systemic lupus erythematosus  
Acute rheumatic carditis
4. *Dermatologic diseases*  
Pemphigus  
Severe erythema multiforme (Stevens-Johnson syndrome)  
Exfoliative dermatitis  
Bullous dermatitis herpetiformis  
Severe seborrheic dermatitis  
Severe psoriasis  
Mycosis fungoides
5. *Allergic states*  
Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in:  
Bronchial asthma  
Contact dermatitis  
Atopic dermatitis  
Serum sickness  
Seasonal or perennial allergic rhinitis  
Drug hypersensitivity reactions  
Urticarial transfusion reactions  
Acute noninfectious laryngeal edema (epinephrine is the drug of first choice)
6. *Ophthalmic diseases*  
Severe acute and chronic allergic and inflammatory processes involving the eye, such as:  
Herpes zoster ophthalmicus  
Iritis, iridocyclitis  
Chorioretinitis  
Diffuse posterior uveitis and choroiditis  
Optic neuritis  
Sympathetic ophthalmia  
Anterior segment inflammation  
Allergic conjunctivitis  
Keratitis  
Allergic corneal marginal ulcers

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**Section 16: OTHER INFORMATION (continued)**

7. *Gastrointestinal diseases*  
To tide the patient over a critical period of the disease in:  
Ulcerative colitis (Systemic therapy)  
Regional enteritis (Systemic therapy)
8. *Respiratory diseases*  
Symptomatic sarcoidosis  
Berylliosis  
Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy  
Loeffler's syndrome not manageable by other means  
Aspiration pneumonitis
9. *Hematologic disorders*  
Acquired (autoimmune) hemolytic anemia  
Idiopathic thrombocytopenic purpura in adults (I.V. only: I.M. administration is contraindicated)  
Secondary thrombocytopenia in adults  
Erythroblastopenia (RBC anemia)  
Congenital (erythroid) hypoplastic anemia
10. *Neoplastic diseases*  
For palliative management of:  
Leukemias and lymphomas in adults  
Acute leukemia of childhood
11. *Edematous states*  
To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type, or that due to lupus erythematosus
12. *Miscellaneous*  
Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy  
Trichinosis with neurologic or myocardial involvement
13. *Diagnostic testing of adrenocortical hyperfunction*
14. *Cerebral Edema* associated with primary or metastatic brain tumor, craniotomy, or head injury.  
Use in cerebral edema is not a substitute for careful neurosurgical evaluation and definitive management such as neurosurgery or other specific therapy.

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**Section 16: OTHER INFORMATION (continued)****B. By intra-articular or soft tissue injection:**

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Synovitis of osteoarthritis  
 Rheumatoid arthritis  
 Acute and subacute bursitis  
 Acute gouty arthritis  
 Epicondylitis  
 Acute nonspecific tenosynovitis  
 Post-traumatic osteoarthritis.

**C. By intralesional injection:**

Keloids  
 Localized hypertrophic, infiltrated, inflammatory lesions of: lichen planus, psoriatic plaques, granuloma annulare and lichen simplex chronicus (neurodermatitis)  
 Discoid lupus erythematosus  
 Necrobiosis lipoidica diabetorum  
 Alopecia areata  
 May also be useful in cystic tumors of an aponeurosis or tendon (ganglia).

Refer to Luitpold / American Regent's prescribing information for further information at [http://www.americanregent.com/product\\_index.asp](http://www.americanregent.com/product_index.asp)

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