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.
WARNING!	
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.
Potential Health Effects: See Section 11 for more information	
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. 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_2). **Caution:** CO_2 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).
Protection for firefighters: 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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Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)	
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)

Section 10: STABILITY AND REACTIVITY	
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.

Section 11: TOXICOLOGY INFORMATION	
Acute Effects	
Oral (LD_{50})	LD_{50}: 6500 mg/kg oral - mouse
Subcutaneous (LD_{50})	No data available
Intravenous (LD_{50})	LD_{50}: 794 mg/kg intravenous - mouse
Dermal (LD_{50})	No data available
Intraperitoneal (LD_{50})	LD_{50}: 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)	
Chronic Effects	
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) hypoplasticanemia
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 diabeticorum
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

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