

MATERIAL SAFETY DATA SHEET

Dexamethasone Sodium Phosphate, USP Powder

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SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Dexamethasone Sodium Phosphate, USP Powder
COMMON NAME: Dexamethasone Sodium Phosphate
CHEMICAL NAME: Dexamethasone Sodium Phosphate
SYNONYMS: Dexamethasone Sodium Phosphate, USP
CHEMICAL FORMULA: $C_{22}H_{28}FNa_2O_8P$
CHEMICAL FAMILY: Glucocorticoid

SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	OSHA PEL	ACGIH TLV	IDLH
Dexamethasone Sodium Phosphate	2392-39-4	NE	NE	NE

Specific amounts are considered proprietary information.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

Symptoms of Overexposure by Route of Exposure: Suppression of adrenal gland secretion; Cushing's Syndrome; water retention; electrolyte imbalance; hyperglycemia.

WARNING! Dexamethasone Sodium Phosphate should be administered under the supervision of a qualified physician.

SECTION 4: FIRST AID MEASURES

- Skin Exposure: Thoroughly wash with mild soap and water. Remove contaminated clothing immediately. If irritation develops, seek medical attention.
- Eye Exposure: Immediately flush eye with copious amounts of water and seek medical attention.
- Inhalation: Inhalation exposure is not expected to occur. If symptoms occur, remove to fresh air and seek medical attention.
- Ingestion: Flush out mouth with water. Seek medical attention. Never induce vomiting to an unconscious or convulsing person.

SECTION 5: FIRE / EXPLOSION HAZARDS AND FIRE-FIGHTING MEASURES

Flash Point: NA

Autoignition Temperature: NA

Flammable Limits (in air by volume, %): Lower: NA Upper: NA

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 full protective clothing and a self contained breathing apparatus. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, 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.

SECTION 6: SPILL AND LEAK PROCEDURES

Spill and Leak Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Clean up material and place in an appropriately labeled disposal container. Avoid breathing dust. Avoid runoff into storm sewers and ditches which lead to waterways. Consult local authorities regarding notification requirements.

SECTION 7: HANDLING AND STORAGE

Work and Hygiene Practices: As with all chemicals, avoid generating dust/vapors and 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.

Storage and Handling Practices: Store under refrigeration. Store away from foodstuffs. Wash hands before eating. Avoid contact with eyes, skin, and clothing.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Ventilation and Engineering Controls: Use adequate ventilation (local exhaust) when working with this material.

Respiratory Protection: No special requirements under normal conditions. Use an approved respirator if necessary.

Eye Protection: Although the risk from eye exposure is minimal, prudence recommends the use of safety glasses.

Hand Protection: No special requirements under normal condition of use. However, rubber gloves should be worn as necessary and during spill clean-up.

Body Protection: No special requirements under normal conditions of use. If dust is generated use appropriate protective face and body covering.

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<u>Boiling Point:</u>	NA	<u>Vapor Pressure:</u>	NA
<u>Melting/Freezing Point:</u>	NA	<u>pH:</u>	NA
<u>Water Solubility:</u>	Soluble	<u>Water Reactive:</u>	No
<u>Specific Gravity (Water =1):</u>	NA	<u>Evaporation Rate (Butyl acetate = 1):</u>	NA
<u>Appearance / Odor:</u>	Crystals		

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under labeled storage conditions.

Incompatible Materials: None.

Hazardous Polymerization: Will not occur.

Hazardous Decomposition: None.

Conditions to Avoid: None known at this time.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: Intravenous Rat LD₅₀ = 159 mg/kg
Intravenous Mouse LD₅₀ = 112 mg/kg
Oral Mouse LD₅₀ = 1,800 mg/kg

Note: Prolonged application to the eye could cause increased intra-ocular pressure and reduced visual function. Intro-articular injection into a load-bearing joint could cause joint damage. Rapid intravenous injection of large doses could cause cardiovascular collapse.

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC, or OSHA.

Irritancy of Product: During normal use of product no eye contact should occur.

Sensitization to the Product/Adverse Reactions: Systemic fungal infections are aggravated by exposure.

Reproductive Information: This medicine should be used with caution during pregnancy, and only if the expected benefit to the mother is greater than any possible risk to the fetus. Seek medical advice from a doctor. The safety of this medicine during breastfeeding has not been established. Seek medical advice from a doctor.

Mutagenicity: ND

Embryotoxicity / Teratogenicity / Reproductive Toxicity: Pregnancy Category C. 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. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism. Systematically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from corticosteroids, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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

SECTION 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/Animals/Aquatic Life: No information is currently available on the environmental impact of this product.

SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: Dispose of material according to local disposal regulations or company operating procedures.

U.S. EPA Waste Number: None

SECTION 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

North American Emergency Response Guidebook Number (1996): 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

SECTION 15: REGULATORY INFORMATION**U.S. REGULATIONS:**

U.S. SARA Reporting Requirements: 311/312 Hazard Categories: Immediate Health, 313 Reportable Ingredients: None

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities: 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 a chemical known to the State of California to cause developmental and reproductive effects.

SECTION 16: OTHER INFORMATION**DEFINITIONS OF ABBREVIATIONS USED:**

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
CERCLA:	Comprehensive Environmental Response Compensation and Liability Act
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC ₅₀ :	Medial Lethal Concentration
LD ₅₀ :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
NA:	Not Available
NE:	Not Established
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration

PEL: Permissible Exposure Limit
SARA: Superfund Amendment and Reauthorization Act
STEL: Short Term Exposure Limit
TLV: Threshold Limit Value
TSCA: Toxic Substances Control Act
TWA: Time Weighted Average

SECTION 17: DISCLAIMER

The information contained in this Material Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. Paddock Laboratories, Inc. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages from use or reliance on the above information.