

**MATERIAL SAFETY DATA SHEET**

Issued: 09/07/94	Prepared by: Gary Wong
Revised: 09/30/04	Manager EHS
Revision: 02	Core No. 044

**1. PRODUCT AND COMPANY INFORMATION**

**Product Name:** Dexamethasone Sodium Phosphate Ophthalmic Solution USP, 0.1%  
**Generic Name:** Same  
**NDC No.** 24208-720-02 (5 ml)

**Legal Category:** Prescription only medicine, filled inside a plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

**Drug Composition:** Glucocorticoid

BAUSCH & LOMB INCORPORATED  
 8500 Hidden River Parkway  
 Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST  
 Emergency: (800) 227-1427 24 hrs

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

Description	CAS #	TLV (mg/m <sup>3</sup> )		PEL (mg/m <sup>3</sup> ) % Content
Dexamethasone	50-02-2	NE	NE	0.1
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Sodium Phosphate, Sodium Chloride, Polysorbate 80, Edetate Disodium, Sodium Bisulfite, Benzalkonium Chloride

---

### 3. HAZARDS IDENTIFICATION

---

\*\*\*\*\*

#### EMERGENCY OVERVIEW

Plastic bottle in cardboard box. Clear, colorless to slightly yellow, with rose like odor aqueous solution.

\*\*\*\*\*

#### POTENTIAL HEALTH HAZARDS

**Carcinogenicity:** (NTP) No (IARC) No (OSHA) No

**Eye:** May cause irritation or burning sensation on installation and hypersensitivity (anaphylactic) in some individuals. It has been shown, though not in humans, that through large doses or prolonged topical administration, glucocorticoids may be systemically adsorbed by pregnant mothers and produce fetal abnormalities. Systematically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Systemic toxicity reactions include reversible hypothalamic-pituitary-adrenal axis gland suppression, manifestations of Cushing's syndrome, intercranial hypertension, hyperglycemia and glycosuria.

**Skin:** May cause irritation and localized hypersensitivity in some individuals with itching, swelling and diffused redness of the skin.

**Ingestion:** May cause irritation and hypersensitivity in some individuals. Large doses may induce vomiting, diarrhea, adrenal gland suppression, Cushing's syndrome, water retention, electrolyte imbalance and hyper-glycemia.

**Inhalation:** May cause irritation and hypersensitivity in some individuals.

**Chronic Effects:** May cause hypersensitivity. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation.

**Target Organs:** Eyes, skin, digestive tract, kidney and brain.

**Medical Conditions Aggravated by Long Term Exposure:** Anaphylactic cross-reactions may occur for corticosteroids and antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. This medication is contraindicated for patients with herpes simplex, vaccinia and varicella infections. As with other anti-microbial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Preexisting conjunctival or systemic fungal infections may be aggravated. Appropriate measures should be taken if this occurs.

---

#### 4. FIRST AID MEASURES

---

**Eyes:** Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

**Skin:** Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

**Ingestion:** Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

**Note to Physicians:** Additional details are available on the package insert or in the Physicians Desk Reference.

---

#### 5. FIRE FIGHTING MEASURES

---

**Flammable Properties:** Flash point: NE Method: NE

**Hazardous Products:** Emits toxic fumes.

**Extinguishing Media:** Dry chemical, carbon dioxide, halon, water fog and foam for surrounding materials. Water spray will froth if sprayed into the burning material.

**Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

---

#### 6. ACCIDENTAL RELEASE MEASURES

---

**Large/Small Spills:** Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

---

#### 7. HANDLING AND STORAGE

---

**Handling:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

**Storage:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

---

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

---

**Engineering Controls:** In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor, levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

**Eye Protection:** (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

**Skin Protection:** Thick impermeable gloves and protective clothing.

**Respiratory Protection:** (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

**Warning:** **Do not use air-purifying respirators in oxygen-depleted environments.** No respiratory protection is required in the clinical or home environment.

**Other:** None

**Ventilation:** Recommended

**Contaminated Equipment:** Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

---

## 9. CHEMICAL & PHYSICAL PROPERTIES

---

**Appearance & Odor:** Clear, colorless to slightly yellow, aqueous solution, with rose like odor.

Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Complete	Percent Volatile by Volume:	<1

---

## 10. STABILITY AND REACTIVITY

---

**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

**Hazardous Decomposition Products:** Emits toxic fumes.

**Hazardous Polymerization:** Should not occur.

---

## 11. TOXICOLOGY

---

**Summary of Risks:** Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material

CAS #

50-02-2

### **Dexamethasone Base**

May cause irritation to eyes, skin and respiratory tract. May also cause pain, redness, and pus containing blisters. Prolonged or repeated contact may cause hypersensitivity (anaphylactic) in some individuals. May cause allergic reaction if inhaled, ingested or in contact with the skin. Adverse reactions include suppression of adrenal gland secretion, Cushing's syndrome, water retention, electrolyte imbalance and hyperglycemia. Studies in animals indicate that topical adrenocorticoids, when used in large amounts, can be systemically absorbed and may cause fetal abnormalities. Human pregnancy studies have not been done. IP-rat LD50 54 mg/kg, SC-rat LD50 14 mg/kg.

---

## 12. ECOLOGICAL INFORMATION

---

**Chemical Fate Information:** Product administered to patients presents a negligible impact on the environment.

---

## 13. DISPOAL INFORMATION

---

**Dispose of material according to Federal, State, and Local regulations.** The method typically used is incineration.

**EPA Designations:** RCRA Hazardous Waste: Not Listed

**SARA Title III:** Not Listed

---

**14. TRANSPORTATION INFORMATION**

---

**Transportation Data:** Not classified as hazardous by DOT regulations.

---

**15. REGULATORY INFORMATION**

---

**DOT Designations:** Not classified as hazardous by DOT regulations.

**EPA Designations:** RCRA Hazardous Waste  
(40 CFR 261.33) Not Listed

**FDA Designations:** Prescription only medication.  
NDC No. 24208-720-02 (5 ml)

**OSHA Designations:** (29 CFR 1910.1000, Table Z)  
Not Listed

**SARA Title III:** Not listed under Section 313 of Toxic Release Reporting.

**CALIFORNIA PROPOSITION 65:** Not Listed

---

**16. OTHER INFORMATION**

---

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than