

**AMERICAN REGENT LABORATORIES, INC.
MATERIAL SAFETY DATA SHEET**

PRODUCT NAME: DEXAMETHASONE SODIUM PHOSPHATE INJECTION

MANUFACTURER: LUITPOLD PHARMACEUTICALS, INC.
ONE LUITPOLD DRIVE
SHIRLEY, NY 11967

**EMERGENCY
TELEPHONE
NUMBER:** (800) 645-1706

SECTION I: IDENTITY

Common Name - Dexamethasone Phosphate
Chemical Name - 9-Fluoro-11b,17,21-trihydroxy-16a-methylpregna-1,4-diene-3,20-dione
21-(dihydrogen phosphate) disodium salt
Chemical Family - Glucocorticoid; steroid
Chemical Formula - $C_{22}H_{28}FNa_2O_8P$
CAS No. - 2392-39-4
RTECS No. - TU4056000

SECTION II: HAZARDOUS INGREDIENTS/ACTIVE INGREDIENTS

<u>COMPONENT</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>
Dexamethasone Phosphate	Not Established	Not Established

SECTION III: PHYSICAL & CHEMICAL CHARACTERISTICS

DESCRIPTION: Dexamethasone Sodium Phosphate Injection, USP is a sterile, nonpyrogenic solution of dexamethasone sodium phosphate in Water for Injection. (pH 7.0 - 8.5)

Appearance & Odor - Clear colorless to pale yellow solution; odorless
Boiling Point - N/A
Solubility in Water - Soluble
Vapor Pressure - N/A
Vapor Density - N/A

AMERICAN REGENT LABORATORIES, INC.
Subsidiary of Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
Shirley, New York 11967

Page 2 of 4
DEXAMETHASONE SODIUM PHOSPHATE

SECTION IV: FIRE & EXPLOSION DATA

Flash Point - N/A

Extinguisher Media - Water spray, carbon dioxide, dry chemical, or foam as appropriate for surrounding fire and materials.

Flammable Limits - (LEL) - N/A
(UEL) - N/A

Unusual Fire and Explosion Hazards - Emits toxic fumes.

Hazardous Decomposition Products - Dexamethasone Sodium Phosphate emits toxic fumes when heated to decomposition.

Special Fire Fighting Procedures - Firefighters should use self-contained breathing apparatus and protective clothing.

SECTION V: REACTIVITY DATA

Stability - Stable

Conditions/Materials to Avoid - Exposure to excessive heat and light may cause decomposition. Do not mix with other drugs.

Hazardous Polymerization - Will not occur

SECTION VI: HEALTH HAZARD DATA

Primary Routes of Exposure - Inhalation, Ingestion, and Skin Absorption.

Chemical Listing as Carcinogen

National Toxicology Program - No

IARC Monographs - No

OSHA - No

AMERICAN REGENT LABORATORIES, INC.
Subsidiary of Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
Shirley, New York 11967

DEXAMETHASONE SODIUM PHOSPHATE**Signs and Symptoms of Overexposure**

Acute - Eye, skin, and/or respiratory tract irritation. Suppression of adrenal gland secretion, hyperglycemia, water retention.

Chronic - Possible hypersensitization

Emergency & First Aid Procedures

Inhalation: Remove person to fresh air. Remove contaminated clothing. Seek medical attention.

Ingestion: Flush mouth out with water. Seek medical attention.

Skin Contact: Remove contaminated clothing. Flush area with water. Seek medical attention.

Eye Contact: Flush with water. Seek medical attention.

FOR ADDITIONAL INFORMATION, REFER TO THE PRODUCT INSERT.

SECTION VII: PROTECTIVE EQUIPMENT DATA

Ventilation - Local exhaust recommended

Respiratory - N/A, however, NIOSH-approved respirator should be available.

Eyes - Safety Goggles

Gloves - Disposable surgical latex gloves

Clothing - Disposable protective apparel (protect exposed skin).

SECTION VIII: STORAGE & HANDLING DATA

Precautions - As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the product. Do not mix with other drugs.

AMERICAN REGENT LABORATORIES, INC.
Subsidiary of Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
Shirley, New York 11967

DEXAMETHASONE SODIUM PHOSPHATE

SECTION IX: ACCIDENTAL SPILL PROCEDURES/WASTE DISPOSAL DATA

Containment/Clean-up - Wear recommended personal protective equipment. Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with paper towels. Wipe working surfaces to dryness, then wash with soap and water.

Waste Disposal - Though not EPA regulated, waste should be disposed of in accordance with federal, state, and local regulations. Do not mix with other substances.

NOTICE: The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for his or her particular purpose. Luitpold Pharmaceuticals, Inc. assumes no additional liability or responsibility resulting from the use of, or reliance on, this information.

Prepared by: Barbara Goulding Date: 2/27/02
 Barbara Goulding, Supervisor, Regulatory Affairs

F:\DocShare\M\SDSA\Dexamethasone Sodium Phosphate.doc

AMERICAN REGENT LABORATORIES, INC.
 Subsidiary of Luitpold Pharmaceuticals, Inc.
 One Luitpold Drive
 Shirley, New York 11967