



Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V,
Gurgaon - 122 016, Haryana, INDIA

Dexamethasone Tablets

Section I - IDENTITY

Common/Trade Name: Dexamethasone Tablets

Chemical Name: Pregna-1,4-diene-3,20-dione,9-fluoro-11-beta,17,21-trihydroxy-16-alpha-methyl-,21-(dihydrogen phosphate) disodium salt

Synonyms: Decadron phosphate, Decdan, Dexacort, Dexadreson, Dexagro, Megacort, Soldesam, Solu-Decadron, Spersadox, Turbinaire; Fluoro-9-trihydroxy-11,17,21-methyl-16-pregnadiene-1 sodium phosphate; Disodium dexmethasone phosphate; Dexamethasone disodium phosphate; Sodium Dexamethasone Phosphate

Manufacturer's Name: GETWELL PHARMACEUTICALS
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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Name	CAS #	% by Weight
Dexamethasone sodium phosphate	2392-39-4	100

Toxicological Data on Ingredients: Dexamethasone sodium phosphate: ORAL (LD50): Acute: 1800 mg/kg [Mouse].

Section III - HEALTH HAZARD DATA

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female [POSSIBLE]. Repeated or prolonged exposure is not known to aggravate medical condition.

Section IV - FIRST AID MEASURES

Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:

Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO₂), halogenated compounds, phosphates. Some metallic oxides.

Fire Hazards in Presence of Various Substances:

Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Section VI - ACCIDENTAL RELEASE INFORMATION**Small Spill:**

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section VII - HANDLING AND STORAGE**Precautions:**

Keep away from heat. Keep away from sources of ignition. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.

Storage:

Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 8°C (46.4°F). Refrigerate.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT**Engineering Controls:**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical state and appearance: Solid. (Crystalline powder.)

Odor: Not available.
Taste: Not available.
Molecular Weight: 516.41 g/mole
Color: White to yellowish.
pH (1% soln/water): 7.5 [Basic.]
Boiling Point: Not available.
Melting Point: 233°C (451.4°F) - 235 C
Critical Temperature: Not available.
Specific Gravity: Not available.
Vapor Pressure: Not applicable.
Vapor Density: Not available.
Volatility: Not available.
Odor Threshold: Not available.
Water/Oil Dist. Coeff.: Not available.
Ionicity (in Water): Not available.
Dispersion Properties: See solubility in water.
Solubility: Easily soluble in cold water.

Section X - STABILITY AND REACTIVITY

Stability: The product is stable.
Instability Temperature: Not available.
Conditions of Instability: Excess heat, incompatible materials, dust generation
Incompatibility with various substances: Reactive with oxidizing agents.
Corrosivity: Not available.
Special Remarks on Reactivity: Hygroscopic; keep container tightly closed.
Special Remarks on Corrosivity: Not available.
Polymerization: Will not occur.

Section XI - TOXICOLOGICAL INFORMATION

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 1800 mg/kg [Mouse].

Chronic Effects on Humans: DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female [POSSIBLE].

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects and birth defects (teratogenic)

Special Remarks on other Toxic Effects on Humans:

Potential Health Effects: Skin: May cause skin irritation with erythema, burning or itching, dryness, folliculitis, hypertrichosis, acneform eruptions, hypopigmentation, urticaria, petechiae and ecchymoses,

skin atrophy, striae, miliaria. May cause allergic contact dermatitis Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation. May cause anaphylactoid or hypersensitivity reactions. Ingestion: May cause gastrointestinal tract irritation with nausea, malaise, abdominal distention, peritonitis, hiccups. May cause ulcerative esophagitis, peptic ulcer with possible subsequent perforation and hemorrhage. May affect behavior/central nervous system (convulsions, vertigo, headache, psychic disturbances), cardiovascular system, brain, endocrine system (menstrual irregularities, suppression of growth in children, Cushing's syndrome, adrenocortical and pituitary unresponsiveness, decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics), eyes (posterior subcapsular cataracts, increased intraocular pressure, glaucoma), metabolism (weight gain or weight loss, increased appetite or decreased appetite, electrolyte imbalance, water retention), musculoskeletal system (muscle weakness, loss of muscle mass, steroid myopathy, Osteoporosis, vertebral compression fractures, pathologic fractures of long bones, tendon rupture), skin (impaired wound healing, thin fragile skin, petechiae and ecchymoses, erythema, burning or itching, urticaria), blood (thromboembolism). May cause anaphylactoid or hypersensitivity reactions.

Section XII - ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are as toxic as the product itself.

Special Remarks on the Products of Biodegradation: Not available.

Section XIII - DISPOSAL INFORMATION

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section XIV - TRANSPORTATION INFORMATION

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section XV - REGULATORY INFORMATION

Federal and State Regulations: TSCA 8(b) inventory: Dexamethasone sodium phosphate

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):

R40- Possible risks of irreversible effects. R62- Possible risk of impaired fertility. S2- Keep out of the reach of children. S36/37-Wear suitable protective clothing and gloves.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

Section XVI - OTHER DATA

References:

Physician's Gen Rx, 1995. Registry of Toxic Effects of Chemical Substances (RTECS) -Manufacturer's Material Safety Data Sheet.

Other Special Considerations: Not available.

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