



Material Safety Data Sheet

MSDS Number: 1102363
Revision date: 08/12/2004
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102363
Product name: Dexamethasone Sodium Phosphate Injection, USP
Product code: NDC 0641-6282-15, NDC 0641-0372-25, NDC 0641-2273-41, NDC 0641-2276-41, NDC 0641-6272-15, NDC 0641-0367-25, NDC 0641-2277-41, NDC 0641-0367-21, NDC 0641-0372-44, NDC 0641-2273-39, NDC 0641-2273-01
Synonyms: None
Chemical Family: Steroid
Product Type: Regulated Prescription Drug
Container Information: 4 mg/mL in 1 and 5 mL Dosette® syringes or vials, 5 mL and 30 mL multiple dose vials. 10 mg/mL in 1 mL Doseette® syringes or vials, 10 mL multiple dose vials.
Product Use: Pharmaceutical.

Supplier:
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Dexamethasone Sodium Phosphate 2392-39-4	0.4-1	None	None
Benzyl Alcohol 100-51-6	1	UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	Xn;R20/22
Sodium Citrate Anhydrous 68-04-2	<2	None	None
Water 7732-18-5	>96	None	None
Sodium Sulfite Anhydrous 7757-83-7	<0.2	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: Avoid skin contact. May cause respiratory tract irritation.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Single large doses is considered to be virtually without harmful effects based upon similar drug data.

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Skin contact: May cause irritation and/or allergic reactions.

Eye contact: May cause irritation and/or allergic reactions.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

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.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Notes to physician: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	>214°F (>101°C)
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions: No information available.

Methods for cleaning up: If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

7. HANDLING AND STORAGE

Handling:
Technical measures/precautions: Wash thoroughly after handling.

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Storage:**Technical measures/storage conditions:**

Keep containers tightly closed in a cool, well-ventilated place. Keep at temperatures between 15 and 30 °C (59 to 86°F). Protect from light. Avoid freezing.

Incompatible products:

No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Dexamethasone Sodium Phosphate 2392-39-4	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	None
Sodium Citrate Anhydrous 68-04-2	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None
Sodium Sulfite Anhydrous 7757-83-7	None	None	None	None	None	None

Engineering measures:

No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:**Respiratory protection:**

Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection:

Use chemical resistant, impervious gloves.

Skin and body protection:

Work uniform or laboratory coat.

Eye protection:

Safety glasses. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES
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Physical state:

Liquid

Appearance:

Aqueous solution

Color:

Colorless

Odor:

Not available.

pH:

7.0 - 8.5

Molecular weight:

Not available.

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Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Dexamethasone Sodium Phosphate 2392-39-4	Oral LD50 Mouse = 1800 mg/kg Intravenous LD50 Mouse = 794 mg/kg
Benzyl Alcohol 100-51-6	Oral LD50 Rat = 1230 mg/kg Oral LD50 Mouse = 1360 mg/kg Dermal LD50 Rabbit = 2 gm/kg
Sodium Citrate Anhydrous 68-04-2	None
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg
Sodium Sulfite Anhydrous 7757-83-7	Oral LD50 Mouse = 820 mg/kg

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Acute toxicity: May cause skin and eye irritation. Large doses of similar drugs suppressed immune function based on animal data.

Chronic toxicity: Overexposure may cause gastrointestinal effects, skin disorders, eye disorders, cardiovascular effects, and musculoskeletal effects. See patient package insert for additional information. Contains material which may cause damage to the following organs: skin, eye, lens or cornea.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: Considered fetotoxic based on similar drug data.

FDA Pregnancy Category Not available.

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Eotoxicity Data
Dexamethasone Sodium Phosphate 2392-39-4	None.	None.	None.	None.
Benzyl Alcohol 100-51-6	= 23 mg/L EC50 water flea	LC50 (96 hr) fathead minnow:460 mg/L:Static, 18-22 °C.;LC50 (96 hr) bluegill:10 mg/L:Static.	None.	= 63.7 mg/L EC50 Photobacterium phosphoreum = 71.4 mg/L EC50 Photobacterium phosphoreum
Sodium Citrate Anhydrous 68-04-2	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.
Sodium Sulfite Anhydrous 7757-83-7	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
 UN Number: None
 DOT Packing Group: None
 DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
 TDG UN/NA Number: None
 TDG Packing Group: None
 TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
 ADR Proper shipping name: None
 ADR UN/NA number: None
 ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
 IATA UN NUMBER: None
 IATA Primary Hazard: None
 IATA Packing group: None
 ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
 IMDG Hazard Class and Division: None
 IMDG Packing Group: None
 IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Dexamethasone Sodium Phosphate	0.4-1	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate Anhydrous	<2	Not Listed	Not Listed	Not Listed	Not Listed
Water	>96	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Sulfite Anhydrous	<0.2	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

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Product name: Dexamethasone Sodium Phosphate Injection, USP

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Dexamethasone Sodium Phosphate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Not Listed	Present	Not Listed	Not Listed	Present	[present]	Not Listed
Sodium Citrate Anhydrous	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Sulfite Anhydrous	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product complies with EINECS

Risk Phrases:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
Additional product codes.

Additional information:
Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation

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End of safety data sheet: