



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Betamethasone Sodium Phosphate	
Other means of identification		
Catalog number	1068004	
CAS number	151-73-5	
Synonyms	Betamethasone 21-phosphate disodium salt	
Chemical name	Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11beta,16beta)-	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Acute toxicity, inhalation	Category 2
	Serious eye damage/eye irritation	Category 2B
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Harmful if swallowed. Fatal if inhaled. Causes eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection.

<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Potent pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Betamethasone Sodium Phosphate	Betamethasone 21-phosphate disodium salt	151-73-5	100

### 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician or poison control center immediately. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<b>Most important symptoms/effects, acute and delayed</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. Endocrine system effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Treatment of corticosteroid overdose may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
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<b>Methods and materials for containment and cleaning up</b>	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>7. Handling and storage</b>	
<b>Precautions for safe handling</b>	As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Skin protection</b>	
<b>Hand protection</b>	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Other</b>	Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
<b>Respiratory protection</b>	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

<b>Appearance</b>	Appearance descriptions are general information and not specific to any USP lot.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder. Crystalline solid.
<b>Color</b>	White. Off-white.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.

<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa (77 °F (25 °C))
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Freely soluble.
<b>Solubility (other)</b>	Acetone: Practically insoluble. Chloroform: Practically insoluble. Methanol: Freely soluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Corticosteroid.
<b>Molecular formula</b>	C22H28FNa2O8P
<b>Molecular weight</b>	516.4
<b>pH in aqueous solution</b>	7.5 - 9 Solution 1%

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Acids. Bases. Oxidizing agents. Reducing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. POx. F-. NaOx.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Fatal if inhaled.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Causes eye irritation.
<b>Ingestion</b>	Harmful if swallowed.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Corticosteroids: Fluid and electrolyte imbalance. Adrenal suppression. Immunosuppression. Cushing's syndrome. High blood pressure. Gastrointestinal disturbances. Headache. Lightheadedness. Weakness. Visual disturbances. Mood or mental status changes. Infection. Thinning skin. Swelling. Bruising. Bone fractures. Back pain. Joint pain. Tremors. Menstrual irregularities. Impotence.
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### Information on toxicological effects

<b>Acute toxicity</b>	Fatal if inhaled. Harmful if swallowed.
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<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Betamethasone Sodium Phosphate (CAS 151-73-5)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	0.071 - 0.73 mg/l
<b>Oral</b>		
LD50	Mouse	1607 mg/kg
	Rat	1877 mg/kg
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	

**Serious eye damage/eye irritation**

Causes eye irritation.

**Local effects**

Eye irritation test

Result: Mild: Reversible ocular irritation; reversible within 7 days.

Species: Rabbit

Skin irritation test

Result: Not irritating.

Species: Rabbit

**Respiratory or skin sensitization**

**Respiratory sensitization**

Knowledge about health hazard is incomplete.

**Skin sensitization**

Knowledge about health hazard is incomplete.

**Germ cell mutagenicity**

Knowledge about mutagenicity is incomplete.

**Mutagenicity**

Ames test (Salmonella typhimurium; E. coli)

Result: Negative.

In vitro human lymphocyte chromosome aberration

Result: Positive.

In vivo mouse micronucleus test, Bone marrow

Result: Equivocal.

Mutagenicity: Mammalian cell mutagenicity assay (CHO/HGPRT)

Result: Negative.

**Carcinogenicity**

Knowledge about carcinogenicity is incomplete.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

Suspected of damaging fertility or the unborn child.

Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.

Adverse fetal effects were seen in animal studies with a related material.

**Specific target organ toxicity - single exposure**

Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure**

Causes damage to organs (endocrine system) through prolonged or repeated exposure.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Further information**

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**12. Ecological information**

**Ecotoxicity**

Product	Species	Test Results
Betamethasone Sodium Phosphate (CAS 151-73-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50 Daphnia magna	1.9 mg/l, 48 hours

**Persistence and degradability**

Minimally biodegradable.

**Bioaccumulative potential**

No data available.

**Mobility in soil**

No data available.

**Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

### 13. Disposal considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### DOT

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Betamethasone Sodium Phosphate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	II

#### IATA

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Betamethasone Sodium Phosphate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	II
<b>Other information</b>	

**Passenger and cargo aircraft** Allowed with restrictions.

**Cargo aircraft only** Allowed with restrictions.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**DOT; IATA**



**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

### 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### Toxic Substances Control Act (TSCA)

##### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Acute toxicity (any route of exposure)  
 Serious eye damage or eye irritation  
 Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 08-18-2010**Revision date** 08-29-2022**Version #** 04

**Disclaimer** USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.