

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Betamethasone Sodium Phosphate USP
Commercial Name Not available.
Product Use Active Pharmaceutical Ingredient
Restrictions On Use Any use apart from the active pharmaceutical ingredient
Product Code 55-1951
Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Reproductive toxicity, category 2 Reproductive toxicity, effects on or via lactation Specific target organ toxicity -
CFR 1910.1200 repeated exposure, category 2
Signal Word WARNING
Hazard Statement(s) Harmful if swallowed. Suspected of damaging the unborn child. May cause harm to breast-fed children. May cause damage to organs through prolonged or repeated exposure.

Pictogram(s) or Symbol(s)**Precautionary Statement(s):**

Prevention P201 Obtain special instructions before use P260 Do not breathe dust P263 Avoid contact during pregnancy/while nursing P281 - Use personal protective equipment as required
Response P308+P313 If exposed or concerned: get medical advice/attention
Storage Not available
Disposal P501- Dispose of contents/container in accordance with local /regional /national/international regulation

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Betamethasone Sodium Phosphate USP
% By Weight 100
CAS# 151-73-5
Molecular Weight 516.41 g/mole
Chemical Formula C₂₂H₂₈FN₂O₈P
Synonym(s) 9-Fluoro-11,17,21-trihydroxy-16-me hylpregna-1,4-diene-3,20-dione sodium phosphate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Betamethasone Sodium Phosphate USP	151-73-5	100	Not Available.	ORAL (LD50):Acute: 1607mg/kg [Mouse].

Section 4: First-Aid Measures

Inhalation	Avoid breathing dust that may be generated by handling the product. Move to fresh air in a well-ventilated area. Consult your doctor if the exposure was significant in terms of quantity or time.
Skin Contact	Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice immediately and show the label to the doctor.
Eye Contact	Wash immediately with large amounts of water or normal saline solution. Keep eyelids open with the finger. Get medical advice and show him the label.
Ingestion	If swallowed wash mouth with water provided the person is conscious. Get medical advice immediately and show container or label.
Symptoms/Effects	
Acute	Possible acute effects are: anaphylactic reactions or hypersensitivity, thromboembolism, nausea, malaise, fatigue, allergic dermatitis, urticaria
Delayed	Delayed effects and symptoms related to this substance are not foreseen.

Immediate Medical Attention

- Medical monitoring: The competent doctor defines medical examinations to be carried out in order to protect the health of workers.
- Antidotes, if known: Unknown - Contraindications: Unknown - Immediate treatment at workplace: In case of reactions described under "Hazard Indications" or other severe, immediate, or persistent reactions, call a physician or contact the nearest poison control center. Show product label and the present MSDS.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Nebulised water, chemical powder A/B/C, foam, CO, halogenated hydrocarbons, (Halon/NAF)

Unsuitable Extinguishing Media

Unsuitable extinguishing media are not known

Products of Combustion

Thermal decomposition and combustion may produce toxic fumes containing, COx, HF, Na2O, phosphorus oxides and other substances in case of incomplete decomposition. The substance is an organic powder, explosive mixtures with air may be formed under certain conditions (e.g. temperature, pressure, particle size, moisture, combustive concentration).

Firefighters Special Equipment and Precautions

Don't try to extinguish the fire without an autonomous respiratory device (SCBA) and protective adapted clothes. Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

Section 6: Accidental Release Measures

-For non-emergency personnel - Eye: Wear suitable protective devices, (see section 8) - Skin: Wear suitable clothes with full body protection. - Inhalation: In case of fire and/or explosions avoid to breathe smokes and vapours. Use a respiratory device autonomous (SCBA) and adapted protective clothes. The vapours can be eliminated with nebulized water. Methods and material for containment and cleaning up - Containment procedures: Collect all of the material scattered on the ground with protective suitable equipment. - Cleaning up procedures: Recover the substance by suction or other mechanic means and wash the area with plenty of water and cleanings. Store the recovered product in wait of the skilled disposal society. If the release happened in highway or in a public place, suitable expedients should be adopted in order to protect people from any risk. Environmental precautions: In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water.

Section 7: Handling and Storage

Handling: Handle away from sparks and flames - sources of ignition. Handle in a well ventilated place. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8). Keep the substance away from drains, surface or ground waters. Hygiene: Do not eat, drink and smoke in the working areas. Wash hands after handling the substance. Remove contaminated clothing and protective equipment before entering eating areas. Storage: The risk management procedures described in this section are consistent with the physical and chemical properties reported in section 9. The substance is not classified for any physical and chemical properties and no risk management is foreseen. Risk Management measures related to : - Potential ignition sources: Don't expose to heat sources. Procedure to control other effects - Weather conditions: - Ambient pressure: - Temperature: - Sunlight: - Humidity - Vibration: It is not expected any procedure of restriction. It is not expected any procedure of restriction. Store at a temperature of $+5\pm 3^{\circ}\text{C}$. Protect from light. Don't store in a damp place. No procedure of restriction is expected. The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available (ingredients in the substance are not yet REACH registered). Material to keep the integrity of the substance - Stabilisers: - Antioxidants: Use of stabilisers is not expected Use of antioxidants is not expected Other advice - Ventilation requirements - Specific design of storage rooms - Quantity limits for storage - Packaging compatibilities

Requested on the base of the storage of the substance Not requested on the base of the classification Not requested on the base of the classification See also 10.5

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
Engineering Controls	The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario described in the Reach Registration Dossier is not available.
Personal Protection	<p>The adoption of the most appropriate Personal Protective Equipment is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available (ingredients in the substance are not yet REACH registered).</p> <p>a) Eye and Face protection b) Skin protection - Hands protection Safety goggles as for EN 166; facial shield Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/EEC. The gloves material must be waterproof and stable against the substance content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, thickness. Material: nitrile (nitrile rubber), hypoallergenic Thickness: not inferior to 0.12 mm - Other, body protection Select the suitable protective equipment based on the activity of use and possible exposure. Wear protective gloves, boots, bodysuit and other devices in accordance with EN 14605 in case of spurts or EN 13982 in case of powders c) Respiratory protection: When the risk evaluation foresees the need to use respiratory devices with assisted ventilation, use a powder filter like P1, P2 and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU). In case of brief exposure or low pollution use respiratory filter. In case of deeper and longer exposures use self-contained breathing. d) Thermal hazards Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.</p>

Section 9: Physical and Chemical Properties

Appearance	White or almost white powder		
Odor	Odorless		
Odor Threshold	Not available		
Melting Point	Not available.	pH	7.5-9 (1% aq. solution)
Freezing Point	Not available	Vapor Pressure	8.62e ⁻²¹ mmHg at 25C ^[2]
Boiling Point/Range	669.6 °C at 760 mmHg	Vapor Density	Not available.
Decomposition temperature	Not available	Viscosity	Not available.
Partition Coefficient: n-octanol/water	0.651 (predicted)	Evaporation Rate	Not available
Flash Point	358.7C[2]	Autoignition temperature	Not available
Flammability	Not available	Flammability or Explosive Limits:	
		Lower	Not available
		Upper	Not available
Solubility(ies)	Freely soluble in water. Slightly soluble in alcohol, practically insoluble in methylene chloride		
Other	Very hygroscopic		

Section 10: Stability and Reactivity

Reactivity	This substance is considered not reactive under the normal conditions of the usage. Reacts in contact with strong oxidizing agents
Chemical Stability	The product is stable at the normal condition of temperature and pressure and if stored in airtight containers in well ventilated and cool place
Hazardous Polymerization	Corrosivity: Non-corrosive in presence of glass. Hazardous polymerization will not occur.
Conditions to Avoid	Avoid exposure to light, air, moisture and excessive heat
Incompatible Materials	Strong oxidising agents
Hazardous Decomposition Products	If heated at high temperatures, decomposes releasing fumes and toxic gases of CO _x , HF, Na ₂ O and other substances in case of incomplete decomposition

Section 11: Toxicological Information

RTECS	TU4056500
Acute Toxicity	

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- Oral: LD50 (rat) = 1877mg/kg LD50 (mouse) = 1607mg/kg - Dermal: Not found after bibliographic research. - Inhalation: Not found after bibliographic research. - Other information: LD50 subcutaneous (rat) = 1265 mg/kg LD50 intraperitoneal (rat) = 1179 mg/kg LD50 intravenous (rat) = 1276 mg/kg LD50 intramuscular (rat) = 1291 mg/kg LD50 subcutaneous (mouse) = 1363 mg/kg LD50 intravenous (mouse) = 1304 mg/kg LD50 intramuscular (mouse) = 1166 mg/kg Chronic Effects on Humans: Causes damage to the following organs: lungs, mucous membranes. Germinal cell mutagenicity Not found after bibliographic research. Betamethasone In vitro: Bacterial gene mutation assay: negative Mammalian cell gene mutation assay: negative Mammalian chromosome aberration test: ambiguous with metabolic activation Mammalian chromosome aberration test: negative without metabolic activation In vivo: Micronucleus assay: At 48 hour sampling time, a statistically significant increase in micronucleated polychromatic erythrocytes was observed in males (but not females) given 250 and 500 (but not 1000) mg/kg bw/day. Reproductive toxicity: The administration of corticosteroids to pregnant animals showed reproductive toxicity. In reproduction studies, corticosteroids induced malformations (cleft palate and skeletal malformations) and intrauterine growth retardation. However, the effects were observed only at exposures considered sufficiently in excess the maximum human exposure, indicating little relevance to human use. The Gur C. et al. supports that GCS do not represent a major teratogenic risk in humans. Corticosteroids are excreted in breast milk in amounts presumed not high, but the long-term administration and/or high doses of corticosteroids may cause a reduction in height growth, body weight gain, intracranial hypertension (swelling of the fontanelle, headaches, bilateral papilledema), reduced plasma concentrations of cortisol, lack of response to adrenocorticotrophic hormone stimulation test (ACTH). The corticosteroid use by breastfeeding women can cause a decrease in the volume of secreted milk. Detectable adverse effect: hyperglycemia, osteoporosis, amenorrhea, mood disorders, edema and hypertension caused by sodium retention. The risk of systemic toxicity is greater in the case of exposure to high doses for long periods of time. The sudden suspension of exposure may cause adrenal insufficiency, manifested by fever, malaise, myalgia, arthralgia, breathing difficulty (dyspnea), anorexia, nausea, vomiting, dehydration.

Skin Corrosion/Irritation

In predisposed individuals may cause mild irritation

Serious Eye Damage/Irritation

in predisposed individuals may cause mild irritation

Respiratory or Skin Sensitization

Dermal: Not found after bibliographic research. Respiratory: Not found after bibliographic research

Germ Cell Mutagenicity

Not found after bibliographic research

Carcinogenicity

Not found after bibliographic research

Reproductive Toxicity

The administration of corticosteroids to pregnant animals showed reproductive toxicity

Routes of Entry

Inhalation, ingestion, Skin contact, Eye contact

Symptoms Related to Exposure

Risk of increased blood pressure, risk of eye damage, liver damage and edema

Potential Health Effects

Not available

Target Organ(s)

Repeated exposure: Corticosteroids can cause immune suppression, suppression of the hypothalamic-pituitary-adrenal axis

Section 12: Ecological Information**Ecotoxicity**

Not found after bibliographic research

Persistence and Degradability

Not found after bibliographic research

Bioaccumulative Potential

Log Kow (predicted) of 0.651 with a BCF (predicted) of 1 suggests a very low potential for bioconcentration in aquatic organisms.

Mobility in Soil

Koc (predicted) of 1 suggests a very high mobility in soil. For other physicochemical properties see point 9

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Other Adverse Effects

Environmental hazards Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Section 13: Disposal Considerations**Waste Disposal**

Sewage disposal is not allowed. Incineration.

Disposal of Container

Incineration

Other Considerations

Not available

Section 14: Transport Information**DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information**Regulations**

Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires emergency planning based on Threshold Planning Quantities (TPQs) and release reporting based on Reportable Quantities (RQs) in 40 CFR 355 (used for SARA 302, 304, 311 and 312). Components present in this product at a level which could require reporting under the statute are: NONE Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires submission of annual report release of toxic chemicals that appear in 40 CFR 372 (used for SARA 313). This information must be included in all MSDSs that are copied and distributed for this material. Components present in this product at a level which could require reporting under the statute are: NONE; Pennsylvania Right-To-Know, Hazardous substance List, Hazardous Substances and Special hazardous Substances on the list must be identified when present in products. Components present in this product at a level which could require reporting under the statute are: NONE Massachusetts Right-To-Know, Substance List (MSL) Hazardous Substances and Extraordinarily Hazardous Substances on the MSL must be identified when present in products. Components present in this product at a level which could require reporting under the statute are: NONE Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) requires notification of the National Response Center of release of quantities of Hazardous Substances equal or greater than the reportable quantities (RQs) in 40 CFR 302.4. Components present in this product at a level which could require reporting under the statute are: NONE

Other

WHMIS CLASS D-2A: Material causing other toxic (Canada) effects (VERY TOXIC).;DSCL (EEC) R38- Irritating to skin. R41- Risk of serious damage to eyes. R43- May cause sensitization by skin contact.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.;Splash goggles.

Section 16: Other Information

Not available.