



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Betamethasone</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1066009	
<b>CAS number</b>	378-44-9	
<b>Chemical name</b>	9-Fluoro-11 $\beta$ ,17,21-trihydroxy-16 $\beta$ -methylpregna-1,4-diene-3,20-dione	
<b>Recommended use</b>	For analytical laboratory use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	Customer Service	301-881-0666
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	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, inhalation	Category 2
	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>	Fatal if inhaled. 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>	Do not breathe dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling.
<b>Response</b>	If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If exposed or concerned: Get medical advice/attention.
<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		378-44-9	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

### 4. First-aid measures

<b>Inhalation</b>	Remove person to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological 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.
<b>Methods and materials for containment and cleaning up</b>	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. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

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.

### Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Exposure limit values

#### Industrial Use Material

Betamethasone (CAS 378-44-9)

#### Type

TWA

#### Value

1 micrograms/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

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.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

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.

#### Skin protection

##### Hand protection

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.

##### Other

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.

#### Respiratory protection

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.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

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

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Crystalline powder.

#### Color

White. Off-white.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

> 447.8 - < 473 °F (> 231 - < 245 °C) (decomposes)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

### Upper/lower flammability or explosive limits

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

Vapor pressure	<0.0000001 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
<b>Solubility(ies)</b>	
Solubility (water)	Insoluble.
Solubility (other)	Methanol: Sparingly soluble. Chloroform: Very slightly soluble. Ether: Very slightly soluble. Acetone: Sparingly soluble. Ethanol: Sparingly soluble.
Partition coefficient (n-octanol/water)	1.94
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
<b>Other information</b>	
Chemical family	Corticosteroid.
Molecular formula	C22H29FO5
Molecular weight	392.46 g/mol

## 10. Stability and reactivity

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

## 11. Toxicological information

### Information on likely routes of exposure

Inhalation	Fatal if inhaled.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics	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

Acute toxicity	Fatal if inhaled.
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Product	Species	Test Results
Betamethasone (CAS 378-44-9)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	0.4 mg/l, 4 hours
<b>Oral</b>		
LD50	Mouse	> 4500 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**

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

**Local effects**

0.1 % Skin irritation  
Result: Negative.  
Species: Human  
Severity: Mild.  
Eye irritation  
Result: Negative.  
Species: Rabbit  
Skin irritation  
Result: Negative.  
Species: Rabbit  
Severity: Mild.

**Respiratory or skin sensitization**

**Respiratory sensitization** Knowledge about health hazard is incomplete.

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

in vitro hapten-specific sensitization method  
Result: Not sensitizing.  
Species: Mouse  
Organ: Skin.  
in vivo (LLNA)  
Result: Not sensitizing.  
Species: Mouse  
Organ: Skin.

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

**Mutagenicity**

Ames test  
Result: Negative.  
Chromosome aberration  
Result: Equivocal.  
Micronucleus test  
Result: Equivocal.  
Mutagenicity: Mammalian gene mutation assay  
Result: Negative.

**Carcinogenicity**

**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.

**Reproductivity**

0.05 - 0.3 mg/day Reproductivity  
Result: Increased induction of cleft palate.  
Species: Rat  
1 mg/kg/day Developmental  
Result: Retarded growth, pale swollen skin, decreased movement, and hypoplasia of the thymus and lung in offspring.  
Species: Rat

**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** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability** Minimally biodegradable.

**Bioaccumulative potential**

**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

**Disposal instructions** 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.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** 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).

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

**UN number** UN2811  
**UN proper shipping name** Toxic solid, organic, n.o.s. (Betamethasone)  
**Transport hazard class(es)**  
**Class** 6.1  
**Subsidiary risk** -  
**Packing group** II  
**Environmental hazards**  
**Marine pollutant** No.

### IATA

**UN number** UN2811  
**UN proper shipping name** Toxic solid, organic, n.o.s. (Betamethasone)  
**Transport hazard class(es)**  
**Class** 6.1  
**Subsidiary risk** -  
**Packing group** II  
**Other information**  
**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)  
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 Proposition 65

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. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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** 11-26-2024

**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 compiled by USP staff from sources considered to be scientifically reliable but has not been independently verified by USP. USP does not guarantee the accuracy or completeness of the information from these sources included herein nor should the statements contained herein be considered an official expression by USP. USP does not independently create or develop the information included in this safety data sheet. 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.