

## 1. Identification

<b>Product identifier</b>	<b>Alclometasone Dipropionate</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1012757	
<b>Chemical name</b>	Pregna-1,4-diene-3,20-dione, 7-chloro-11-hydroxy-16-methyl-17,21-bis(1-oxopropoxy)-, (7 alpha, 11 beta, 16 alpha)-	
<b>Synonym(s)</b>	Alclometasone 17,21-dipropionate	
<b>Recommended use</b>	Specified quality tests and assay 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>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<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>	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2B
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)
<b>OSHA hazard(s)</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Causes skin irritation. 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. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>	If on skin: Wash with plenty of water/. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. 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.	
<b>Storage</b>	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>	Not classified.	

### 3. Composition/information on ingredients

#### Substance

#### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Alclometasone Dipropionate	Alclometasone 17,21-dipropionate	66734-13-2	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Remove contaminated clothing. Wash off with soap and plenty of water. If skin irritation occurs: Get medical advice/attention.
<b>Eye contact</b>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes and mucous membranes. Fluid and electrolyte disturbances. Hypertension. Mood or mental changes.
<b>Indication of immediate medical attention and special treatment needed</b>	Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary. Treatment should be symptomatic and supportive. [Poisindex 2010]
<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>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
<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.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

### 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, 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. Use of a designated area is recommended for handling of potent materials.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. 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	Type	Value
Alclometasone Dipropionate (CAS 66734-13-2)	TWA	35 micrograms/m <sup>3</sup>

**Biological limit values** No biological exposure limits noted for the ingredient(s).

<b>Appropriate engineering controls</b>	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
<b>Other</b>	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
<b>Respiratory protection</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	White to off-white crystalline powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	413.6 - 420.8 °F (212 - 216 °C) ; also reported as 191 ° C
<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 applicable.
<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>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility in water</b>	Insoluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## Other information

<b>Chemical family</b>	Corticosteroid.
<b>Molecular formula</b>	C <sub>28</sub> H <sub>37</sub> ClO <sub>7</sub>
<b>Molecular weight</b>	521.04
<b>Solubility (other)</b>	Slightly soluble in propylene glycol and in chloroform; moderately soluble in hexylene glycol; sparingly soluble in acetone.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<b>Chemical stability</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	Strong acids. Oxidizers. Strong bases.
<b>Hazardous decomposition products</b>	Cl <sup>-</sup> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Due to lack of data the classification is not possible.
<b>Eye contact</b>	Causes eye irritation.

**Symptoms related to the physical, chemical, and toxicological characteristics**  
Mineralocorticoid effects: Swelling. Confusion. Lightheadedness. Nausea. Vomiting. Numbness. Tremors.  
Glucocorticoid effects: Bone fractures. Back pain. Joint pain or stiffness. Weakness. Increased appetite. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Increased hair growth. Acne. Redistribution of body fat. Menstrual irregularities. Impotence. Headache. Increased sweating. Eye pain. Change in vision. Mental or behavioral changes.  
Withdrawal effects: Fever. Muscle pain. Joint pain. Malaise.

**Delayed and immediate effects of exposure**  
Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.

**Cross sensitivity**  
Persons sensitive to one corticosteroid may be sensitive to this material also.

**Medical conditions aggravated by exposure**  
Corticosteroids: Heart disease. High blood pressure. Diabetes. Epilepsy. Glaucoma. Hypothyroidism. Osteoporosis. Peptic ulcer. Systemic fungal infection. Mental disorders. Impaired liver or kidney function.

### Acute toxicity

Product	Species	Test Results
Alclometasone Dipropionate (CAS 66734-13-2)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rat	> 75 mg/kg
<i>Inhalation</i>		
LC50	Rat	> 4.94 mg/l
<i>Oral</i>		
LD50	Mouse	> 5000 mg/kg
	Rat	3593 mg/kg

**Skin corrosion/irritation**  
Causes skin irritation.

**Serious eye damage/eye irritation**  
Causes eye irritation.

### Local effects

1 % Skin irritancy  
Result: Moderate irritation.  
Species: Human  
Eye irritancy test in animals  
Result: Slight, reversible conjunctival irritation.  
Skin irritancy test in animals  
Result: Mild irritation.

**Respiratory sensitization**  
Due to lack of data the classification is not possible.

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

**Sensitization**

Skin sensitization test in animals  
Result: No sensitization.

**Germ cell mutagenicity**

Due to lack of data the classification is not possible.  
Data from germ cell mutagenicity tests were not found.

**Mutagenicity**

Ames test in *S. typhimurium*, with and without activation.  
Result: Negative.  
In vitro assays in mouse lymphoma cells and erythrocytes  
Result: Negative.  
Mutagenicity tests in *E. coli*, with and without activation.  
Result: Negative.

**Carcinogenicity**

Due to lack of data the classification is not possible.  
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

**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**

<= 0.75 mg/kg/day Reproductivity and development studies,  
administered topically.  
Result: Maternal toxicity; fetotoxicity; teratogenicity.  
Species: Rabbit  
<= 1200 mg/kg/day Reproductivity and development studies,  
administered orally.  
Result: Maternal toxicity; fetotoxicity; teratogenicity.  
Species: Rabbit  
Reproductivity and development studies, administered orally.  
Result: Teratogenicity.  
Species: Rat

**Specific target organ toxicity - single exposure**

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

**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.

**12. Ecological information****Ecotoxicity**

No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential**

Not available.

**Mobility in soil**

Not available.

**Other adverse effects**

Not available.

**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**

Not available.

**Hazardous waste code**

Not available.

**Waste from residues / unused products**

Dispose of in accordance with local regulations. 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**

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

Not regulated as a hazardous material by DOT.

**IATA**

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

## 15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

### Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) 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)	No
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)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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)

## 16. Other information, including date of preparation or last revision

Issue date 08-04-2010

Revision date 01-31-2014

Version # 02

Further information Not available.

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**Revision Information** This document has undergone significant changes and should be reviewed in its entirety.