


# SAFETY DATA SHEET

## Prednisolone Oral Solution, USP 15 mg/5 mL

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Prednisolone Oral Solution, USP 15 mg/5 mL	
<b>Synonyms:</b>	Pregna-1,4 -diene -3, 20 - dione, 11, 17, 21-trihydroxy-, (11β)	
<b>National Drug Code (NDC):</b>	50383-042-24 50383-042-48	
<b>Recommended Use:</b>	Prednisolone Oral Solution, USP is indicated for the following conditions: endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, edematous states, gastrointestinal diseases, tuberculous meningitis, trichinosis and systemic dermatomyositis (polymyositis).	
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045	
<b>Contact Telephone:</b>	1-800-932-5676	
<b>E mail:</b>	customer.service@akorn.com	
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)	

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.	
<b>Health Hazards:</b>	Serious Eye Damage/Eye Irritation	Category 2A
<b>Symbol(s):</b>		
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H319 Causes serious eye irritation.	
<b>Precautionary Statement(s):</b>	P264 Wash hands and other exposed areas thoroughly after handling.  P280 Wear protective gloves/protective clothing/eye protection/face protection.	

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P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 +  
 P351  
 +  
 P338

P337 IF eye irritation persists: Get medical advice/attention.  
 +  
 P313

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: None.  
 Supplementary Information: None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Prednisolone	Pregna-1,4 -diene -3, 20 - dione, 11, 17, 21-trihydroxy-, (11β)	50-24-8	C <sub>21</sub> H <sub>28</sub> O <sub>5</sub>	360.45	0.3%
Alcohol	Ethanol; Dehydrated Alcohol	64-17-5	C <sub>2</sub> H <sub>6</sub> O	46.07	5%

The formula also contains Benzoic Acid, 0.1% as a preservative; Citric Acid, Edetate Disodium, Glycerin, Propylene Glycol, Purified Water, Sodium Saccharin, Sucrose, Artificial Wild Cherry Flavor, FD&C Blue #1 and FD&C Red #40.

### 4. FIRST AID MEASURES

#### Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

#### Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.
<b>Medical Conditions Aggravated by Exposure:</b>	No data available.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

#### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

#### Specific Hazards Arising from the Chemical

<b>Hazardous Combustion Products:</b>	Not determined.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment and Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.

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**Methods for Cleaning Up:** Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Avoid release to the environment. Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information and in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Do not refrigerate.

**Specific End Use:** Pharmaceutical drug product.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Prednisolone	NIOSH REL	0.4 mcg/m <sup>3</sup>
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m <sup>3</sup>
	NIOSH TWA	1,000 ppm; 1,900 mg/m <sup>3</sup>
	ACGIH TLV STEL	1,000 ppm

*NIOSH: National Institute for Occupational Safety and Health; REL: Recommended Exposure Limits; OSHA: Occupational Safety and Health Administration; PEL: Permissible Exposure Limits; TWA: Time Weighted Average; ACGIH: American Conference of Governmental Industrial Hygienists; TLV: Threshold Limit Value; STEL: Short Term Exposure Limit.*

**Engineering Controls:** None required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** None required for the normal use of this product. 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).

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<b>Eyes Protection:</b>	None required for the normal use of this product. 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>Hand Protection:</b>	Not required for the normal use of this product. Chemically compatible gloves should be worn when working with large quantities. 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 non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
<b>General Hygiene Considerations:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Light pink syrup.
<b>Odor:</b>	Cherry odor.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	Same as water.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

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### 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>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	Will not occur.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Freezing.
<b>Incompatible Materials:</b>	Strong oxidizing agents.
<b>Hazardous Decomposition Products:</b>	Does not undergo explosive decomposition.

### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

<b>Inhalation:</b>	No data available.
<b>Ingestion:</b>	No data available.
<b>Skin Contact:</b>	No data available.
<b>Eye Contact:</b>	Causes serious eye irritation.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

#### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Prednisolone	Rat	Oral	LD <sub>50</sub>	3,857 mg/kg
	Mouse	Oral	LD <sub>50</sub>	1,680 mg/kg
Alcohol	Rat	Oral	LD <sub>50</sub>	7,060 mg/kg
	Mouse	Oral	LD <sub>50</sub>	3,450 mg/kg
	Rat	Inhalation	LD <sub>50</sub>	124.7 mg/l, 4 hours

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### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
Alcohol	Eye Irritancy - Draize Test, 96% ethanol	Rabbit	Moderate Irritant
	Skin Irritancy - Draize Test, 96% ethanol	Rabbit	Not Irritant
	Skin Irritancy - Draize Test, 95% ethanol	Rabbit	Slightly Irritant
	Skin Irritancy – OECD 404	Rabbit	Not Irritant
	Eye Irritancy – OECD 404	Rabbit	Moderate Irritant
	Mouse ear swelling test, 95% ethanol	Mouse	Not sensitizing

### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

**Aspiration Hazard:** No data available.  
**Toxicokinetics/Metabolism:** No data available.  
**Target Organ Effects:** No data available.  
**Systemic Effects:** No data available.  
**Reproductive Effects:** No data available.  
**Carcinogenicity:** No data available.

**National Toxicology Program (NTP):** Not considered to be a carcinogen.

**International Agency for Research on Cancer (IARC):** Not considered to be a carcinogen.

**Occupational Safety and Health Administration (OSHA):** Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Prednisolone	Ide, silver or golden orfe (Leuciscus idus)	LC <sub>50</sub>	>500 mg/l	96 hours
Alcohol	Water flea (Daphnia magna)	EC <sub>50</sub>	7.7-11.2 mg/l	48 hours
	Fathead minnow (Pimephales promelas)	LC <sub>50</sub>	>100 mg/l	96 hours

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<b>Terrestrial Toxicity:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Prednisolone	Yes
Alcohol	Yes

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable



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## U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Prednisolone	Listed	Listed	Not listed
Alcohol	Listed	Listed	Listed

**California Proposition 65:**

Alcohol is listed to cause cancer and birth defects or other reproductive harm.

## 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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