

## SAFETY DATA SHEET

Preparation Date: 6/6/2016

Revision date 1/18/2019

Revision Number: G2

### 1. Identification

#### Product identifier

**Product code:** PR103  
**Product Name:** PREDNISONE, ANHYDROUS, MICRONIZED, USP

#### Other means of identification

**Synonyms:** delta-Cortisone  
 delta-1-Cortisone  
 delta-Cortone  
 17,21-Dihydroxypregna-1,4-diene-3,11,20-trione  
 delta-1-Dehydrocortisone  
 1-Dehydrocortisone  
 1,2-Dehydrocortisone  
 Prednison  
 Prednizon  
 1,4-Pregnadiene-17-alpha,21-diol-3,11,20-trione  
 17-alpha,21-Dihydroxypregna-1,4-diene-3.11.20-trione

**CAS #:** 53-03-2  
**RTECS #** TU4154100  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** Medication. Drug.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Tom Tyner (USA - West Coast)

**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Reproductive toxicity	Category 2
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#### Label elements

**Warning****Hazard statements**

Suspected of damaging fertility or the unborn child

**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**

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

**Precautionary Statements - Response***IF exposed or concerned: Get medical advice/attention***3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Prednisone	53-03-2	100

**4. FIRST AID MEASURES****First aid measures****General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:**

Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If eye irritation persists, consult a specialist.

**Inhalation:**

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

**Ingestion:**

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

**Most important symptoms and effects, both acute and delayed****Symptoms**

May cause eye/skin/respiratory tract irritation

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Glucocorticoids (Corticosteroids): Ingestion may cause osteoporosis and bone fractures, back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia)

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray. Foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous combustion products** Carbon Monoxide, Carbon Dioxide.

**Specific hazards** May be combustible at high temperatures.

**Special Protective Actions for Firefighters**

**Specific Methods:** No information available

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**Methods and material for containment and cleaning up**

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE**

**Precautions for safe handling**

**Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

**Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities****Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

**Incompatible Materials:**

Strong oxidizing agents

<b>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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**Control parameters****National occupational exposure limits****United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Prednisone	53-03-2	None	None	None	None

**Canada**

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Prednisone	53-03-2	None	None	None	None

**Australia and Mexico**

Component	CAS No	Australia	Mexico
Prednisone	53-03-2	None	None

**Appropriate engineering controls****Engineering measures to reduce exposure:**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Individual protection measures, such as personal protective equipment****Personal Protective Equipment**

**Eye protection:** Goggles or Safety glasses with side-shields.

**Skin and body protection:** Long sleeved clothing apron

Gloves

**Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White. Nearly White.
<b>Odor:</b> Odorless.	<b>Taste</b> Bitter after-taste.	<b>Formula</b> C <sub>21</sub> H <sub>26</sub> O <sub>5</sub>
<b>Molecular/Formula weight (g/mole):</b> 358.44	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 230-235 °C/446-455 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm<sup>3</sup>):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> 1.46	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Very slightly soluble in water Slightly soluble in Methanol	

## 10. STABILITY AND REACTIVITY

**Reactivity**  
May react with strong oxidizers

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Incompatible materials. Avoid dust formation.

**Incompatible Materials:** Strong oxidizing agents

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**Hazardous decomposition products:** Carbon oxides.

**Other Information Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**

Inhalation. Ingestion.

### Acute Toxicity

#### Component Information

Prednisone	
CAS No	53-03-2

**LD50/oral/rat** = No information available  
**LD50/oral/mouse** = No information available  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

#### Product Information

**LD50/oral/rat** =  
**Value - Acute Tox** = No information available

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = No information available

**LD50/dermal/rabbit**  
**Value - Acute Tox** = No information available

**LD50/dermal/rat**  
**VALUE - Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor** = No information available  
**VALUE - Gas** = No information available  
**VALUE - Dust/Mist** = No information available

### Symptoms

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**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause irritation of respiratory tract.

**Ingestion** Corticosteroids(glucocorticoids): Nausea, vomiting, headache. May cause bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, increased sweating, eye pain, vision changes, mental and personality changes, swelling, lightheadedness, numbness, tremors, Fluid and electrolyte imbalance (sodium and fluid retention), suppression of calcium absorption and increased calcium excretion, potassium loss, hypokalemic alkalosis, Cushing's syndrome, immune system depression.

**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** Prolonged or repeated eye contact with glucocorticoids/corticosteroids may affect vision (glaucoma, cataracts). Prolonged or repeated skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy). Prolonged or repeated ingestion of corticosteroids may cause osteoporosis and bone fractures due to mobilization of calcium (reduced calcium absorption) and phosphorus, hypokalemia due to increase urinary loss of potassium, development of glaucoma and cataracts, muscle weakness/muscle wasting, swelling of the feet or lower legs due fluid and sodium retention, hip or shoulder pain, irregular heartbeat. It may affect the liver, kidneys, pancreas (pancreatitis), blood (changes in serum composition), behavior/central nervous system (anxiety, nervousness or restlessness, trouble sleeping, mental disturbances such as psychosis, euphoria, depression), protein metabolism, lipid metabolism, carbohydrate metabolism causing insulin resistance, hyperglycemia, diabetes, and the immune system (immunosuppressant) causing increased susceptibility to infections), thinning skin. Repeated ingestion of large doses of corticosteroids may also produce other symptoms typical of hyperactivity of the adrenal gland and overproduction of cortisol (Cushing's Syndrome) such moon-face, buffalo hump, increased bruising, ecchymoses, striae, and acne, menstrual irregularities, amenorrhea, sometimes hirsutism (deepening of the voice in women), and excess hair growth (in women). Corticosteroids may also have an inhibitory effect on wound healing. This may affect persons who have experienced recent nasal ulcers, nasal surgery or nasal trauma.

**Sensitization:** No information available.

**Mutagenic Effects:** Mutations in microorganisms  
Experiments with bacteria and/or yeast have shown mutagenic effects

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Prednisone	53-03-2	Group 3 - Not	Not listed	Not listed	Not listed	Not listed	Not listed

		classifiable - Supplement 7 [1987] Monograph 26 [1981]					
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ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)  
Group 3 - Not classifiable as to its carcinogenicity to humans  
NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

<b>Reproductive toxicity</b>	Suspected of damaging fertility or the unborn child
<b>Reproductive Effects:</b>	No information available
<b>Developmental Effects:</b>	May cause adverse developmental effects based on animal data Possible risk of harm to the unborn child Prednisone can be associated with fetal growth impairment in humans Glucocorticoid medication used during pregnancy has been associated with an increased risk of cleft palate and impaired fetal growth by some studies (REPROTOX)
<b>Teratogenic Effects:</b>	No information available
<b>Specific Target Organ Toxicity</b>	
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Target Organs:</b>	No information available.

## 12. ECOLOGICAL INFORMATION

<b>Ecotoxicity</b>	
<b>Ecotoxicity effects:</b>	No data available.
<b>Persistence and degradability:</b>	No information available
<b>Bioaccumulative potential:</b>	No information available.
<b>Mobility in soil</b>	No information available
<b>Other adverse effects</b>	No information available.

## 13. DISPOSAL CONSIDERATIONS

### Disposal Methods

**Waste from residues / unused products:**  
Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**  
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Prednisone	53-03-2	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class</b>	No information available
<b>Subsidiary Class</b>	No information available
<b>Packing group:</b>	No information available
<b>Emergency Response Guide Number</b>	No information available
<b>Marine Pollutant</b>	No data available
<b>DOT RQ (lbs):</b>	No information available
<b>Special Provisions</b>	No Information available
<b>Symbol(s):</b>	No information available
<b>Description:</b>	No information available

### TDG (Canada)

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No Information available
<b>Description:</b>	No information available

### ADR

<b>UN Number</b>	Not regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Packing group</b>	No information available
<b>Subsidiary Risk:</b>	No information available

### IMDG

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No information available

### RID

<b>UN Number</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing group</b>	No information available

### ICAO (air)

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

### IATA

<b>UN Number</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available

**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** IF exposed or concerned  
**Special Provisions** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
<i>Prednisone</i>	53-03-2	Present	Present KE-10857	Present	Present (9)-743	Not listed	X	Present 200-160-3

**U.S. Regulations**

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Prednisone</i>	53-03-2	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Prednisone</i>	53-03-2	None	None	None	None	None

**U.S. TSCA**

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Prednisone</i>	53-03-2	Not Applicable	Not Applicable

**Canada**

**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

## DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Prednisone	53-03-2	Not Listed	Present

Component	CAS No	CEPA Schedule I - Toxic Substances
Prednisone	53-03-2	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Prednisone	53-03-2	Not listed

## EU Classification

### EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Prednisone	53-03-2	

### EU - CLP (1272/2008)

#### R-phrase(s)

R22 - Harmful if swallowed

R63 - Possible risk of harm to the unborn child

#### S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label

S36/37 - Wear suitable protective clothing and gloves

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Prednisone	53-03-2		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC**

#### Indication of danger:

Xn - Harmful

Xn



## 16. OTHER INFORMATION

**Preparation Date:** 6/6/2016  
**Revision date** 1/18/2019  
**Prepared by:** Sonia Owen

#### Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications.

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**End of Safety Data Sheet**