SAFETY DATA SHEET

1. Identification

Product identifier: Prednisone

Other means of identification:
- Catalog number: 1559006
- Chemical name: Pregna-1,4-diene-3,11,20-trione, 17,21-dihydroxy-
- Synonym(s): 1-Dehydrocortisone

Recommended use: Specified quality tests and assay use only.
Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300
  CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Reproductive toxicity: Category 2
- Specific target organ toxicity, repeated exposure: Category 1 (endocrine system)

OSHA hazard(s): Not classified.

Label elements

- Signal word: Danger
- Hazard statement: Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

Precautionary statement

- Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
- Response: If exposed or concerned: Get medical advice/attention.
- Storage: Store locked up.
- Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisone</td>
<td>1-Dehydrocortisone</td>
<td>53-03-2</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Not available.

Indication of immediate medical attention and special treatment needed
Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary. Treatment should be symptomatic and supportive. [Poisindex 2010]

General information
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

Suitable extinguishing media
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
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. Wash spill site.

7. Handling and storage

Precautions for safe handling
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.

Conditions for safe storage, including any incompatibilities
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

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisone (CAS 53-03-2)</td>
<td>STEL</td>
<td>40 micrograms/m3</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>5 micrograms/m3</td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).
### Appropriate engineering controls

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.

Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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

#### Eye/face protection

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.

#### Skin protection

**Hand protection**

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. This material is extremely potent. 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.

#### Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

#### Respiratory protection

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).

#### Thermal hazards

Not available.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>White or almost white crystalline powder.</td>
</tr>
<tr>
<td><strong>Physical state</strong></td>
<td>Solid.</td>
</tr>
<tr>
<td><strong>Form</strong></td>
<td>Powder.</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless.</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>446 - 455 °F (230 - 235 °C) (decomposes)</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Upper/lower flammability or explosive limits</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Flammability limit - lower (%)</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Flammability limit - upper (%)</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Explosive limit - lower (%)</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Explosive limit - upper (%)</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Solubility in water</strong></td>
<td>Very slightly soluble.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water)</strong></td>
<td>1.46</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not available.</td>
</tr>
</tbody>
</table>

### Other information

- **Chemical family**: Corticosteroid.
- **Molecular formula**: C21H26O5
- **Molecular weight**: 358.44
Solubility (other) Slightly soluble in ethanol, in chloroform, in dioxane, and in methanol.

10. Stability and reactivity

Reactivity No reactivity hazards known.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid None known.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Due to lack of data the classification is not possible.

Inhalation Due to lack of data the classification is not possible.

Skin contact Due to lack of data the classification is not possible.

Eye contact Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics


Cross sensitivity Persons sensitive to other corticosteroids may be sensitive to this material also.


Acute toxicity Due to lack of data the classification is not possible.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisone (CAS 53-03-2)</td>
<td>Mouse</td>
<td>LD50 101 mg/kg, (subcutaneous)</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

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

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

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

Mutagenicity

Ames test in Salmonella, with and without activation
Result: Negative

In vivo chromosome aberration studies in rat bone marrow
Result: Negative

In vivo human studies
Result: Negative; no chromosome damage to peripheral lymphocytes.

Mouse lymphoma studies, without activation
Result: Negative

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

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans.

5 mg/kg/day Long-term carcinogenicity study
Result: Negative
Species: Mouse
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
10 mg/day Epidemiological study
Result: Statistically significant decrease in birth weights of term infants.
Species: Human

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisone (CAS 53-03-2)</td>
<td>IC50</td>
<td>31 mg/l, 72 hours</td>
</tr>
<tr>
<td>Acute Algae</td>
<td>Algae</td>
<td></td>
</tr>
</tbody>
</table>

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
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

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
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)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>SARA 302 Extremely hazardous substance</th>
<th>SARA 311/312 Hazardous chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Hazard - No</td>
<td>Fire Hazard - Yes</td>
<td>Pressure Hazard - No</td>
</tr>
<tr>
<td>Delayed Hazard - No</td>
<td>Reactivity Hazard - No</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.
Food and Drug Administration (FDA) Not regulated.

US state regulations
WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*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 08-20-2010
Revision date 04-22-2013
Version # 03
Further information Not available.
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Revision Information
This document has undergone significant changes and should be reviewed in its entirety.