1. Identification

Product identifier Prednisone Tablets

Other means of identification

Catalog number 1559505

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

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

Serious eye damage/eye irritation Category 2B
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 Causes eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) 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 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.

Storage

Disposal Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition/information on ingredients

Mixture

Hazardous components

Common name and synonyms

CAS number %

Dibasic Calcium Phosphate 7757-93-9 38.5
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></td>
<td>53-03-2</td>
<td>4.5</td>
</tr>
</tbody>
</table>

Non-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>Microcrystalline Cellulose</td>
<td></td>
<td>9004-34-6</td>
<td>52.9</td>
</tr>
<tr>
<td>Sodium Starch Glycolate</td>
<td></td>
<td>9063-38-1</td>
<td>1.8</td>
</tr>
<tr>
<td>Stearic Acid</td>
<td></td>
<td>57-11-4</td>
<td>1.4</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td></td>
<td>557-04-0</td>
<td>0.9</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 or persists.

**Eye contact**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops or persists. If eye irritation persists: Get medical advice/attention.

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

**Most important symptoms/effects, acute and delayed**
Irritation of eyes and mucous membranes.

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

**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.

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.

**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

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline Cellulose (CAS 9004-34-6)</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m³</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline Cellulose (CAS 9004-34-6)</td>
<td>REL</td>
<td>5 mg/m³</td>
<td>Respirable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td>Total</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate (CAS 557-04-0)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Microcrystalline Cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Stearic Acid (CAS 57-11-4)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Exposure limit values

Industrial Use

<table>
<thead>
<tr>
<th>Components</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>TWA</td>
<td>5 micrograms/m³</td>
<td></td>
</tr>
</tbody>
</table>

Biological limit values

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

Exposure guidelines

No exposure standards allocated.

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**

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

**Appearance**

White tablets.

**Physical state**

Solid.

**Form**

Tablet.
Odor: Odorless.
Odor threshold: Not available.
PH: Not available.
Evaporation rate: Not available.
Flammability (solid, gas): Not applicable.
Upper/lower flammability or explosive limits:
- Flammability limit - lower (%): Not available.
- Flammability limit - upper (%): Not available.
- Explosive limit - lower (%): Not available.
- Explosive limit - upper (%): Not available.
Vapor density: Not available.
Relative density: Not available.
Solubility in water: Not available.
Partition coefficient (n-octanol/water): Not available.
Decomposition temperature: Not available.
Viscosity: Not available.

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: Moisture.
Hazardous decomposition products: MgOx, POx, NaOx, CaOx. 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: Causes eye irritation.
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>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic Calcium Phosphate (CAS 7757-93-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rabbit</td>
<td>&gt; 7940 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 10000 mg/kg</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test Results</td>
</tr>
<tr>
<td>------------</td>
<td>---------</td>
<td>--------------</td>
</tr>
<tr>
<td>Magnesium Stearate (CAS 557-04-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Inhalation</em></td>
<td>Rat</td>
<td>&gt; 2 mg/l</td>
</tr>
<tr>
<td><em>Oral</em></td>
<td>Rat</td>
<td>&gt; 10000 mg/kg</td>
</tr>
<tr>
<td><strong>Microcrystalline Cellulose (CAS 9004-34-6)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Dermal</em></td>
<td>Rabbit</td>
<td>&gt; 2 g/kg</td>
</tr>
<tr>
<td><em>Inhalation</em></td>
<td>Rat</td>
<td>&gt; 5.05 mg/l, 4 hours</td>
</tr>
<tr>
<td><em>Oral</em></td>
<td>Rat</td>
<td>&gt; 5 g/kg</td>
</tr>
<tr>
<td><strong>Prednisone (CAS 53-03-2)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Other</em></td>
<td>Mouse</td>
<td>101 mg/kg, (subcutaneous)</td>
</tr>
<tr>
<td><strong>Stearic Acid (CAS 57-11-4)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Dermal</em></td>
<td>Rabbit</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td><em>Oral</em></td>
<td>Rat</td>
<td>4.6 g/kg</td>
</tr>
<tr>
<td><em>Other</em></td>
<td>Mouse</td>
<td>23 mg/kg, (Intravenous)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>21.5 mg/kg, (Intravenous)</td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td><strong>Serious eye damage/eye irritation</strong></td>
<td>Causes eye irritation.</td>
<td></td>
</tr>
<tr>
<td><strong>Local effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>Dermal corrosion study, abraded and intact skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Primary Irritation Index = 0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Duration: 4 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dermal irritation study, abraded and intact skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Primary Irritation Index = 0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organ: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Duration: 24 h</td>
<td></td>
</tr>
<tr>
<td>Stearic Acid</td>
<td>Draize</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Transient mild erythema; not irritating</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organ: Eye</td>
<td></td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>Eye irritation study, not rinsed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Scores = 0 on day 1, 2, 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td>Dibasic Calcium Phosphate</td>
<td>Irritancy test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Mild</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organ: Eye</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irritancy test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Non-irritant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organ: Skin</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline Cellulose</td>
<td>Irritancy test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: Non-irritating; Primary Irritation Index = 0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organ: Skin</td>
<td></td>
</tr>
</tbody>
</table>
Local effects

Microcrystalline Cellulose
Irritancy tests
Result: Minimally irritating; non-irritating
Species: Rabbit
Organ: Eye

Stearic Acid
Patch test - intact and abraded skin
Result: Non-irritant
Species: Rabbit
Organ: Skin
Test Duration: 24 hours
Observation Period: 72 hours

Standard Draize
Result: Mild
Species: Human
Organ: Skin
Test Duration: 3 day

Sensitization

Stearic Acid
7 % Sensitization test
Result: Negative
Species: Human
Organ: Skin

Microcrystalline Cellulose
Sensitization test
Result: Non-sensitizing
Species: Guinea pig
Organ: Skin

Germ cell mutagenicity

Stearic Acid
Ames test in Salmonella typhimurium
Result: Negative

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

Microcrystalline Cellulose
Forward mutation in mouse lymphoma cells, with and without activation.
Result: Negative
In vitro unscheduled DNA synthesis in rat liver cells
Result: Negative

Prednisone
In vivo chromosome aberration studies in rat bone marrow
Result: Negative
In vivo human studies
Result: Negative; no chromosome damage to peripheral lymphocytes.

Microcrystalline Cellulose
In vivo micronucleus assay in mouse bone-marrow erythrocytes
Result: Negative

Stearic Acid
Induction of mitotic crossovers and aneuploidy in Saccharomyces cerevisiae
Result: Negative

Prednisone
Mouse lymphoma studies, without activation
Result: Negative

Microcrystalline Cellulose
Reverse mutation in S.typhimurium and E.coli, with and 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.

Stearic Acid
0.3 % Long-term dietary study
Result: Negative
Species: Rat
Test Duration: 209 days

Prednisone
5 mg/kg/day Long-term carcinogenicity study
Result: Negative
Species: Mouse

Stearic Acid
50 g/kg Feeding study
Result: Non-carcinogenic
Species: Mouse

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

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

Mutagenicity

Stearic Acid
Ames test in Salmonella typhimurium
Result: Negative

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

Microcrystalline Cellulose
Forward mutation in mouse lymphoma cells, with and without activation.
Result: Negative
In vitro unscheduled DNA synthesis in rat liver cells
Result: Negative

Prednisone
In vivo chromosome aberration studies in rat bone marrow
Result: Negative
In vivo human studies
Result: Negative; no chromosome damage to peripheral lymphocytes.

Microcrystalline Cellulose
In vivo micronucleus assay in mouse bone-marrow erythrocytes
Result: Negative

Stearic Acid
Induction of mitotic crossovers and aneuploidy in Saccharomyces cerevisiae
Result: Negative

Prednisone
Mouse lymphoma studies, without activation
Result: Negative

Microcrystalline Cellulose
Reverse mutation in S.typhimurium and E.coli, with and without activation.
Result: Negative

Prednisone Tablets
Material name: Prednisone Tablets
7000 Version #: 02 Revision date: 05-15-2013 Issue date: 09-08-2010
Magnesium Stearate  Implant in mouse bladders
Result: Not carcinogenic

Microcrystalline Cellulose  Long-term carcinogenicity study, implanted in female rats.
Result: Not carcinogenic
Species: Rat
Test Duration: 741 days
Long-term feeding study, 30 % in diet
Result: Not carcinogenic
Species: Rat
Test Duration: 72 weeks

**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**
Prednisone  10 mg/day Epidemiological study
Result: Statistically significant decrease in birth weights of term infants.
Species: Human

Microcrystalline Cellulose  4.6 mg/kg/day Reproductivity and development study, administered in diet.
Result: No adverse effects on the offspring
Species: Rat
Reproductivity and development study, 30% in diet, administered during gestation.
Result: Not teratogenic
Species: Mouse

**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>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic Calcium Phosphate (CAS 7757-93-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Acute</em> Crustacea</td>
<td>EC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td>Prednisone (CAS 53-03-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Acute</em> Algae</td>
<td>IC50</td>
<td>Algae</td>
</tr>
<tr>
<td><em>Acute</em> Other</td>
<td>EC50</td>
<td>Pseudomonas putida</td>
</tr>
<tr>
<td>Stearic Acid (CAS 57-11-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Acute</em> Fish</td>
<td>LC50</td>
<td>Carp (Cyprinus carpio)</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
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - Yes
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

<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>No</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 09-08-2010
Revision date 05-15-2013
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.