1. Identification

Product identifier  Silicified Microcrystalline Cellulose

Other means of identification

Catalog number  1098399

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  Not classified.

OSHA hazard(s)  Not classified.

Label elements

Hazard symbol  No symbol.

Signal word  Not available.

Hazard statement  Not available.

Precautionary statement

Prevention  Not available.

Response  Not available.

Storage  Not available.

Disposal  Not available.

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

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name  Common name and synonyms  CAS number  %

Microcrystalline Cellulose  9004-34-6  98

Colloidal silicone dioxide  112945-52-5  2

4. First-aid measures

Inhalation  Move to fresh air. 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.
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
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
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
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.
Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

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. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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. Clean surface thoroughly to remove residual contamination.

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. OSHA Table Z-3 (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colloidal silicone dioxide (CAS 112945-52-5)</td>
<td>TWA</td>
<td>0.8 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 mppcf</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>Colloidal silicone dioxide (CAS 112945-52-5)</td>
<td>REL</td>
<td>6 mg/m3</td>
<td></td>
</tr>
<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>Microcrystalline Cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/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.

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.

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

Fine white or almost white powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless.

Odor threshold

Not available.

pH

5 - 7.5 (10% w/v suspension)

Melting point/freezing point

500 - 518 °F (260 - 270 °C) (chars)

Flash point

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

Insoluble (dispersible).

Partition coefficient (n-octanol/water)

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Solubility (other) Partially soluble with swelling in dilute alkali; insoluble in organic acids.

Specific gravity

1.58

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

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

11. Toxicological information

Information on likely routes of exposure

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

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
Not available.

Acute toxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colloidal silicone dioxide (CAS 112945-52-5)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50 Mouse</td>
<td>&gt; 15000 mg/kg</td>
</tr>
<tr>
<td>LD50 Rat</td>
<td>&gt; 22500 mg/kg</td>
</tr>
<tr>
<td>Microcrystalline Cellulose (CAS 9004-34-6)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
</tr>
<tr>
<td>LD50 Rabbit</td>
<td>&gt; 2 g/kg</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>LC50 Rat</td>
<td>&gt; 5.05 mg/l, 4 hours</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50 Rat</td>
<td>&gt; 5 g/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Based on available data, the classification criteria are not met.

Local effects

Colloidal silicone dioxide
Eye irritancy
Result: Slight or non-irritancy.
Species: Rabbit

Microcrystalline Cellulose
Irritancy test
Result: Non-irritating; Primary Irritation Index = 0
Species: Rabbit
Organ: Skin
Irritancy tests
Result: Minimally irritating; non-irritating
Species: Rabbit
Organ: Eye
Skin irritancy
Result: Slight or non-irritating.
Species: Rabbit

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

Colloidal silicone dioxide
Guinea pig maximization test
Result: Negative.

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

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

Mutagenicity

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.
**Mutagenicity**

Microcrystalline Cellulose

- In vivo micronucleus assay in mouse bone-marrow erythrocytes
- Result: Negative
- 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.
- Colloidal silicone dioxide
  - Dietary study (5%)
  - Result: No evidence of carcinogenic potential.
  - Species: Mouse
  - Dietary study (5%)
  - Result: No evidence of carcinogenic potential.
  - Species: Rat
- 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**

- Based on available data, the classification criteria are not met.
- Reproductivity
  - Microcrystalline Cellulose
    - 4.6 mg/kg/day Reproductivity and development study, administered in diet.
    - Result: No adverse effects on the offspring
    - Species: Rat
  - Colloidal silicone dioxide
    - 500 mg/kg Reproductive study
    - Result: No evidence of adverse effects.
    - Species: Rat
  - Microcrystalline Cellulose
    - Reproductivity and development study, 30% in diet, administered during gestation.
    - Result: Not teratogenic
    - Species: Mouse

**Specific target organ toxicity - single exposure**

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

**Specific target organ toxicity - repeated exposure**

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

**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.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
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>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</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 07-21-2008
Revision date 02-09-2015
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.