1. Identification

Product identifier  Mineral Oil

Other means of identification
Catalog number  1443952
Chemical name  n/f

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  Serious eye damage/eye irritation  Category 2A
                Aspiration hazard  Category 1

OSHA hazard(s)  Not classified.

Label elements

Signal word  Danger
Hazard statement  Causes serious eye irritation. May be fatal if swallowed and enters airways.
Precautionary statement
Prevention  Wash thoroughly after handling. Wear eye/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 swallowed: Immediately call a poison center/doctor. Do NOT induce vomiting.
Storage  Store locked up.
Disposal  Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition/information on ingredients

Substance
Hazardous components
Chemical name  Mineral Oil
Common name and synonyms  8012-95-1
%  100

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 cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion
Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Aspiration may cause pulmonary edema and pneumonitis.

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

Indication of immediate medical attention and special treatment needed
Treatment of laxative-emollient overdose should be symptomatic and supportive and may include the following:
1. Do NOT induce vomiting.
2. Do NOT administer activated charcoal, unless there is a coingestant with potentially serious side effects.
3. Do NOT administer a cathartic.
4. For excessive diarrhea, treat with high fluid intake and monitoring of fluid and electrolyte status. [Meditext 2007]

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 fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
Do not use water jet as an extinguisher, as this will spread the fire.

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

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

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 vapors. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Absorb spillage with suitable absorbent material. 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>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil (CAS 8012-95-1)</td>
<td>PEL</td>
<td>5 mg/m3</td>
<td>Mist.</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil (CAS 8012-95-1)</td>
<td>REL</td>
<td>5 mg/m3</td>
<td>Mist.</td>
</tr>
<tr>
<td>Mineral Oil (CAS 8012-95-1)</td>
<td>STEL</td>
<td>10 mg/m3</td>
<td>Mist.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil (CAS 8012-95-1)</td>
<td>TWA</td>
<td>5 mg/m3</td>
<td>Inhalable fraction.</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.

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

Clear, colorless liquid.

Physical state

Liquid.

Form

Liquid.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

424.4 - 1189.4 °F (218 - 643 °C)

Flash point

275.00 °F (135.00 °C) Closed Cup
380.00 °F (193.33 °C) Open Cup
> 239.00 °F (> 115.00 °C) (OC) [ASTM D92]

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 pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Insoluble.

Partition coefficient (n-octanol/water)

> 6

Auto-ignition temperature

500 °F (260 °C)

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Heat of combustion (NFPA 30B)
31.5 kJ/g

Kinematic viscosity

>= 38.1 mm2/s
1. Specific gravity

0.845 - 0.905

10. Stability and reactivity

**Reactivity**

Strong oxidizing agents.

**Chemical stability**

Stable at normal conditions.

**Possibility of hazardous reactions**

No dangerous reaction known under conditions of normal use.

**Conditions to avoid**

Avoid temperatures exceeding the flash point.

**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**
  May be fatal if swallowed and enters airways.

- **Inhalation**
  May be fatal if swallowed and enters airways.

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

- **Eye contact**
  Causes serious eye irritation.

**Symptoms related to the physical, chemical, and toxicological characteristics**


**Medical conditions aggravated by exposure**


**Acute toxicity**

Not available.

**Skin corrosion/irritation**

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

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Local effects**

100 mg Skin irritancy test
Result: Mild.
Species: Guinea pig
Test Duration: 24 hours

100 mg Skin irritancy test
Result: Mild.
Species: Rabbit
Test Duration: 24 hours

500 mg Eye irritancy test
Result: Moderate.
Species: Rabbit

**Respiratory sensitization**

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

**Skin sensitization**

Due to lack of data the classification is not possible.

**Germ cell mutagenicity**

Due to lack of data the classification is not possible.

**Data from germ cell mutagenicity tests were not found.**

**Mutagenicity**

Mutagenicity test in S. typhimurium, administered using highly refined mineral oil
Result: Negative.
Sister chromatid exchange test in hamsters
Result: Negative.

**Carcinogenicity**

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

This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

0 - 5 % Dietary carcinogenicity study, using medicinal-grade petroleum and liquid paraffin
Result: No significant increase in tumor incidence.
Species: Rat
Test Duration: 104 weeks

Carcinogenicity study of skin, utilizing application of highly refined, food-grade mineral oils
Result: No skin tumors.
Species: Mouse

Carcinogenicity study, subcutaneous administration of three different grades of medicinal petroleum
Result: No tumors induced.
Species: Mouse
Carcinogenicity study, using intraperitoneal injection of two food-grade mineral oils
Result: Induced plasma-cell neoplasms and reticulum-cell sarcomas in certain strains of mice.
Species: Mouse

Reproductive toxicity
Based on available data, the classification criteria are not met. Hypothrombinemia and hemorrhagic disease of the newborn have occurred following chronic use of mineral oil during pregnancy.

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
May be fatal if swallowed and enters airways.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil (CAS 8012-95-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>LC50 Bluegill (Lepomis macrochirus)</td>
<td>&gt; 10000 mg/l, 96 hours</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
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>No</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: 03-23-2007
Revision date: 07-11-2014
Version #: 02

Further information
USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Revision Information
This document has undergone significant changes and should be reviewed in its entirety.