SAFETY DATA SHEET

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.

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

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Mineral Oil		8012-95-1	100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

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)

Material	Type	Value	Form
Mineral Oil (CAS 8012-95-1)	PEL	5 mg/m3	Mist.

US. NIOSH: Pocket Guide to Chemical Hazards

Material	Type	Value	Form
Mineral Oil (CAS 8012-95-1)	REL	5 mg/m3	Mist.
	STEL	10 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Material	Type	Value	Form
Mineral Oil (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.

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

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	Nausea. Vomiting. Diarrhea. Laxative effects.
Medical conditions aggravated by exposure	Hypersensitivity to material. Appendicitis. Intestinal problems. Ulcerative colitis. Rectal bleeding.
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	Due to lack of data the classification is not possible.
Skin sensitization	Based on available data, the classification criteria are not met.
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

Product		Species	Test Results
Mineral Oil (CAS 8012-95-1)			
Aquatic			
Fish	LC50	Bluegill (Lepomis macrochirus)	> 10000 mg/l, 96 hours

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

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

*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	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.