SAFETY DATA SHEET

1. Identification

Product identifier **Vitamin D Assay System Suitability**

Other means of identification

Catalog number 1717504

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 Skin corrosion/irritation Category 2

OSHA hazard(s) Not classified.

Label elements

Signal word Warning

Hazard statement Causes skin irritation.

Precautionary statement

Prevention Wash thoroughly after handling. Wear protective gloves.

Response If on skin: Wash with plenty of water/soap. If skin irritation occurs: Get medical advice/attention.

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	%
Peanut Oil		8002-03-7	90 - 100
Cholecalciferol		67-97-0	< 0.2
Butylated Hydroxytoluene		128-37-0	< 0.1

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
5,6-trans-Cholecalciferol		22350-41-0	< 0.1

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 — Treat symptomatically.

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 — Dry chemical, foam, carbon dioxide, water fog.

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.

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 vapors. Ensure adequate ventilation. 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. 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)

Components	Type	Value	Form
Peanut Oil (CAS 8002-03-7)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Butylated Hydroxytoluene (CAS 128-37-0)	REL	10 mg/m3	
Peanut Oil (CAS 8002-03-7)	REL	5 mg/m3	Respirable.
		10 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Butylated Hydroxytoluene (CAS 128-37-0)	TWA	2 mg/m3	Inhalable fraction and vapor.

Exposure limit values

Industrial Use

Components	Type	Value
Cholecalciferol (CAS 67-97-0)	TWA	0.01 mg/m3

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.
Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for aerosol-generating procedures.

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 Nearly colorless oil.

Physical state Liquid.

Form Liquid.

Odor Mild, nutty odor.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 36.9 °F (2.7 °C) (peanut oil)

Initial boiling point and boiling range Not available.

Flash point 541.40 °F (283.00 °C) (peanut oil)

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	Practically insoluble. (peanut oil)
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	829.4 °F (443 °C) (peanut oil)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Specific gravity	0.912 - 0.92 (peanut oil)

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	None known.
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	Based on available data, the classification criteria are not met.
Inhalation	Based on available data, the classification criteria are not met.
Skin contact	Causes skin irritation.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Vitamin D analogs: Nausea. Vomiting. Constipation. Diarrhea. Loss of appetite. Weight loss. Black, tarry stools. Increased urination. Thirst. Dry mouth. Metallic taste. Bone or muscle pain. Swelling. Tiredness. Weakness. Headache. Confusion. Depression. Vertigo. Irregular heartbeat. Seizures. Fever. Chills. Red eyes. Increased sensitivity of eyes to light. Itching. Runny nose. Swelling. Decreased sex drive. Component: Weakness. Confusion. Hallucinations. Speech disturbances. Incoordination. Unconsciousness.
Delayed and immediate effects of exposure	Vitamin D analogs: Hypercalcemia. Calcium deposits in tissue. Hyperphosphatemia. Electrolyte imbalance. Edema. Hypercalciuria. Proteinuria. High blood pressure. Kidney damage. Gastrointestinal bleeding. Nervous system problems.
Cross sensitivity	Persons sensitive to peanuts may be sensitive to peanut oil also.
Medical conditions aggravated by exposure	Vitamin D analogs: Hyperphosphatemia. Hypercalcemia. Hypervitaminosis D. Impaired kidney function or kidney stones. Heart disease. Arteriosclerosis. Hypoparathyroidism. Sarcoidosis. Seizure disorders.
Acute toxicity	Based on available data, the classification criteria are not met.

Components	**Species**	**Test Results**
Butylated Hydroxytoluene (CAS 128-37-0)		
Acute		
Oral		
LD50	Mouse	1040 mg/kg
	Rat	890 mg/kg
Cholecalciferol (CAS 67-97-0)		
Dermal		
LD50	Rat	61 mg/kg
Inhalation		
LC50	Rat	0.13 - 0.38 mg/l, 4 hours
Oral		
LD50	Mouse	42500 microg/kg
	Rat	42 mg/kg

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

Local effects

Cholecalciferol	Irritancy test Result: Irritant. Species: Rabbit Organ: Skin Severity: Slight. Irritancy test Result: Non-irritant. Species: Rabbit Organ: Eye
Butylated Hydroxytoluene	Irritancy test (100 mg / 24 hours) Result: Irritant. Species: Rabbit Organ: Eye. Severity: Moderate.
Peanut Oil	Irritancy test (100 mg) Result: Irritant. Species: Guinea pig Organ: Skin Test Duration: 24 hours Severity: Moderate. Irritancy test (100 mg) Result: Irritant. Species: Rabbit Organ: Skin Test Duration: 24 hours Severity: Mild. Irritancy test (100 mg) Result: Irritant. Species: Rat Organ: Skin Test Duration: 24 hours Severity: Moderate. Irritancy test (300 mg/3D-I) Result: Irritant. Species: Human Organ: Skin Severity: Mild.
Butylated Hydroxytoluene	Irritancy test (500 mg/ 48 hours) Result: Irritant. Species: Human Organ: Skin. Severity: Mild. Irritancy test (500 mg/ 48 hours) Result: Irritant. Species: Rabbit Organ: Skin. Severity: Moderate.

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

Skin sensitization Due to lack of data the classification is not possible.
Some studies have suggested that refined peanut oil does not contain the proteins that produce allergic reactions in sensitive individuals.

Sensitization

Cholecalciferol	Sensitization test Result: Non-sensitizing. Species: Guinea pig Organ: Skin

Germ cell mutagenicity Due to lack of data the classification is not possible.

Mutagenicity

Butylated Hydroxytoluene	E. coli Result: Negative. Gene mutation test Result: Negative. Species: Mouse In vitro chromosomal aberrations in Chinese hamster ovary cells Result: Negative. S. typhimurium Ames assay Result: Negative.

Carcinogenicity Due to lack of data the classification is not possible.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

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

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	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)

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)	No
Canada	Domestic Substances List (DSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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 07-20-2005

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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.