



SAFETY DATA SHEET

1. Identification

Product identifier	Retinyl Acetate (Vitamin A)	
Other means of identification		
Catalog number	1716002	
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		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
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
	Reproductive toxicity	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	Causes skin irritation. May damage fertility or the unborn child.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Potent pharmacologically active material.	

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Peanut Oil	Arachis oil	8002-03-7	97
Retinyl Acetate		127-47-9	3

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Irritant effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment for Vitamin A overdose may include the following: Administer activated charcoal as a slurry or perform gastric lavage. Treat fluid loss with IV crystalloid solutions. For elevated intracranial pressure, administer mannitol or corticosteroids. Lumbar puncture with drainage of CSF may alleviate symptoms. Monitor vital signs, fluid and electrolyte status, liver function, and CNS status. Correct anemia and other hematological abnormalities. Neuroleptics may be used to control psychotic reactions. Forced diuresis, dialysis, and hemoperfusion are of no clinical benefit.
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 (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of vapors. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Absorb spillage with suitable absorbent material. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known 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/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Peanut Oil (CAS 8002-03-7)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Mist.

Exposure limit values

Industrial Use

Components	Type	Value
Retinyl Acetate (CAS 127-47-9)	TWA	0.05 mg/m ³

Biological limit values

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

Appropriate engineering controls

No open handling. For laboratory operation, use an engineered local exhaust ventilation (LEV) and/or enclosure or isolator system for procedures where aerosolization of solutions may occur (e.g., vortexing, pipetting, pumping). Control the potential for spills and leaks by securing all connections. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Liquid.

Form

Liquid.

Color

Pale yellow.

Odor

Odorless. Faint odor.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

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 pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Oxidizing agents. Strong acids.
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

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Causes skin irritation.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	Vitamin A toxicity: Sore mouth. Bleeding gums. Diarrhea. Nausea. Vomiting. Dizziness. Drowsiness. Confusion. Unusual excitement. Irritability. Double vision. Severe headache. Peeling of skin.

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Retinyl Acetate (Vitamin A)		
Oral		
LD50	Rat	2740 mg/kg (Vitamin A acetate)
Components	Species	Test Results
Retinyl Acetate (CAS 127-47-9)		
<u>Acute</u>		
Oral		
LD50	Mouse	4100 mg/kg
	Rat	2740 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation

Knowledge about health hazard is incomplete.

Local effects

Retinyl Acetate

Eye Irritation
Result: Negative.
Species: Rabbit

Peanut Oil

Skin Irritation
Result: Positive.
Species: Rabbit
Skin irritation
Result: Irritant.
Species: Human
Severity: Mild.
Skin irritation
Result: Irritant.
Species: Rabbit
Test Duration: 24 hours
Severity: Moderate.

Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about health hazard is incomplete.

Retinyl Acetate

Sensitization
Result: Non-sensitizing.
Species: Guinea pig

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Mutagenicity

Retinyl Acetate

Ames test
Result: Negative with and without activation.
Micronucleus
Result: Negative; Positive with high dose.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

Retinyl Acetate

0 - 95 g/kg Carcinogenicity
Result: Positive for malignant and benign tumors.
Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

May damage fertility or the unborn child.
Retinoids have caused fetal harm resulting in craniofacial, cardiovascular, and central nervous system defects.

Reproductivity

Retinyl Acetate

10 mg/day Gestational: day 20 - 44
Result: Cleft palate as well as craniofacial, skeletal, and urogenital anomalies.
Species: Monkey
Developmental: induced hypervitaminosis
Result: Embryopathies, skeletal malformations as well as cardiovascular and genito-urinary system abnormalities.
Species: Guinea pig
Developmental: tube fed 35000 IU, day 2 - 16
Result: Birth defects and cognitive delays in offspring.
Species: Rat

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Knowledge about health hazard is incomplete.

Further information

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international 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	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
SARA 304 Emergency release notification	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)	Not regulated.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
Classified hazard categories	Skin corrosion or irritation Reproductive toxicity
SARA 313 (TRI reporting)	Not regulated.
Other federal regulations	
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List	Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)	Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 12-26-2019

Version # 01

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