

1. Identification

Product identifier	Paricalcitol Solution	
Other means of identification		
Catalog number	1499414	
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	Flammable liquids	Category 2
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2A
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Highly flammable liquid and vapor. Harmful if swallowed. Causes serious eye irritation.
Precautionary statement	
Prevention	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. In case of fire: Use appropriate media for extinction.
Storage	Store in a well-ventilated place. Keep cool.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Highly potent pharmacologically active material.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Dehydrated Alcohol	Ethanol Alcohol	64-17-5	90 - 100
Paricalcitol	19-Nor-1-alpha,25-dihydroxyvitamin D2	131918-61-1	< 0.1

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital.
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. Use protective equipment appropriate for surrounding materials.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
General fire hazards	Highly flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate personal protective equipment. Avoid inhalation of vapors. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS. Remove sources of ignition. Keep combustibles (wood, paper, oil, etc.) away from spilled material.
Environmental precautions	Prevent further leakage or spillage if safe to do so. 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. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. 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.

U.S. - OSHA Components		
Components	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	PEL	1000 ppm
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)		
Components	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm
ACGIH Components		
Components	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	TWA	1000 ppm
US. ACGIH Threshold Limit Values		
Components	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	STEL	1000 ppm
U.S. - NIOSH Components		
Components	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	IDLH	3300 ppm
US. NIOSH: Pocket Guide to Chemical Hazards		
Components	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm

Exposure limit values

Industrial Use Components		
Components	Type	Value
Paricalcitol (CAS 131918-61-1)	TWA	0.003 micrograms/m3

Biological limit values

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

Appropriate engineering controls

No open handling. Use closed and sealed systems for tasks with the potential for aerosol generation (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	Wear 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 laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. 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. Chose 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

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	Colorless. Clear.
Odor	Not available.
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	
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. Flames. Sparks. Heat.
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

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Causes serious eye irritation.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	For alcohol: Gastrointestinal disturbances. Headache. Dizziness. Drowsiness. Lethargy. Excitement. Depression. Slurred speech. Incoordination. Impaired judgment. Memory loss. Chest pain. Irregular heartbeat. Vitamin D analogs: Hypercalcemia. Gastrointestinal disturbances. Dry mouth. Metallic taste. Bone or muscle pain. Tiredness. Weakness. Headache. Confusion. Irregular heartbeat.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
Dehydrated Alcohol (CAS 64-17-5)		
Acute		
Inhalation		
LC50	Rat	124.7 mg/l, 4 Hours
Oral		
LD50	Mouse	3450 mg/kg
	Rat	7060 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	

Serious eye damage/eye irritation

Causes serious eye irritation.

Local effects

Dehydrated Alcohol

Draize test, 95% ethanol
Result: Slight.
Species: Rabbit
Organ: Skin
Draize test, 96% ethanol
Result: Moderate irritant.
Species: Rabbit
Organ: Eye
Draize test, 96% ethanol
Result: Non irritant.
Species: Rabbit
Organ: Skin
Irritation test, OECD 404
Result: Non irritant.
Species: Rabbit
Organ: Skin
Irritation test: OECD 405.
Result: Moderate irritant.
Species: Rabbit
Organ: Eye

Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

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

Dehydrated Alcohol

Mouse ear swelling test, 95% ethanol
Result: Not sensitizing
Species: Mouse
Organ: Skin

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Mutagenicity

Paricalcitol

Ames test
Result: Negative.
Chromosome aberration
Result: Negative.
Micronucleus test
Result: Negative.
Mouse lymphoma assay
Result: Negative.

Carcinogenicity

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

Paricalcitol

Carcinogenicity
Result: Increased incidence of benign adrenal pheochromocytomas (may be related to the alteration of calcium homeostasis)
Species: Rat
Carcinogenicity
Result: Increased incidence of uterine leiomyomas and leiomyosarcomas
Species: Mouse
Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.

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

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

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Dehydrated Alcohol (CAS 64-17-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	7.7 - 11.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential			
Mobility in soil	No data available.		
Other adverse effects	The product contains volatile organic compounds which have a photochemical ozone creation potential.		

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	Dispose in accordance with all applicable regulations.
Hazardous waste code	D001: Waste Flammable material with a flash point <140 F 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	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

UN number	UN1170
UN proper shipping name	Ethanol solution
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Packaging exceptions	150
Packaging non bulk	202
Packaging bulk	242

IATA

UN number	UN1170
UN proper shipping name	Ethanol solution
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

DOT



**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)

Dehydrated Alcohol (CAS 64-17-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - Yes
 Delayed Hazard - No
 Fire Hazard - Yes
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

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.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

Dehydrated Alcohol (CAS 64-17-5) Low priority

US state regulations**US - California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Dehydrated Alcohol (CAS 64-17-5) Listed: April 29, 2011
 Listed: July 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Dehydrated Alcohol (CAS 64-17-5) Listed: October 1, 1987

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
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
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)
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	08-18-2008
Revision date	03-08-2018
Version #	06
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