



SAFETY DATA SHEET

1. Identification

Product identifier	Calcitriol Solution	
Other means of identification		
Catalog number	1086312	
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 3
	Acute toxicity, dermal	Category 3
	Acute toxicity, inhalation	Category 3
	Reproductive toxicity	Category 2
	Specific target organ toxicity, single exposure	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Highly flammable liquid and vapor. Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled. Causes damage to organs. Suspected of damaging 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. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use explosion-proof electrical/ventilating/lighting equipment. Keep container tightly closed. Use only non-sparking tools. Take precautionary measures against static discharge. Do not breathe mist or vapor. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. Call a poison center/doctor if you feel unwell. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor. If exposed or concerned: Get medical advice/attention. In case of fire: Use appropriate media for extinction.

Storage	Keep cool. Store in a well-ventilated place. Keep container tightly closed. 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	Highly potent pharmacologically active material.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Methyl Alcohol	Wood alcohol	67-56-1	99.9
Calcitriol		32222-06-3	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. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Call a physician or poison control center immediately.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists. For minor skin contact, avoid spreading material on unaffected skin. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Rinse with water. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention if symptoms occur.
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	Provide general supportive measures and 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	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	By heating and fire, harmful vapors/gases 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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
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. 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. Remove sources of ignition. Keep combustibles (wood, paper, oil, etc.) away from spilled 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.

U.S. - OSHA

Components	Type	Value	Form
Methyl Alcohol (CAS 67-56-1)	PEL	200 ppm	Skin

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Methyl Alcohol (CAS 67-56-1)	PEL	260 mg/m ³
		200 ppm

ACGIH

Components	Type	Value	Form
Methyl Alcohol (CAS 67-56-1)	STEL	250 ppm	Skin

US. ACGIH Threshold Limit Values

Components	Type	Value
Methyl Alcohol (CAS 67-56-1)	STEL	250 ppm
	TWA	200 ppm

U.S. - NIOSH

Components	Type	Value	Form
Methyl Alcohol (CAS 67-56-1)	IDLH	6000 ppm	
	STEL	250 ppm	Skin

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Methyl Alcohol (CAS 67-56-1)	STEL	325 mg/m ³
		250 ppm
	TWA	260 mg/m ³
		200 ppm

Exposure limit values

Industrial Use Components	Type	Value
Calcitriol (CAS 32222-06-3)	TWA	0.1 micrograms/m ³

Biological limit values

ACGIH Biological Exposure Indices Components	Value	Determinant	Specimen	Sampling Time
Methyl Alcohol (CAS 67-56-1)	15 mg/l	Methanol	Urine	*

* - For sampling details, please see the source document.

Exposure guidelines

US - California OELs: Skin designation

Methyl Alcohol (CAS 67-56-1)

Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

Methyl Alcohol (CAS 67-56-1)

Skin designation applies.

US - Tennessee OELs: Skin designation

Methyl Alcohol (CAS 67-56-1)

Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Methyl Alcohol (CAS 67-56-1)

Danger of cutaneous absorption

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Methyl Alcohol (CAS 67-56-1)

Can be absorbed through the skin.

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. 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

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

Characteristic.

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	Risk of ignition.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.
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	Toxic if inhaled.
Skin contact	Toxic in contact with skin.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Toxic if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics
Vitamin D analogs: Hypercalcemia. Gastrointestinal disturbances. Dry mouth. Metallic taste. Bone or muscle pain. Tiredness. Weakness. Headache. Confusion. Irregular heartbeat.
Component: Headache. Vertigo. Restlessness. Sedation. Difficulty breathing. Cold, clammy skin. Back pain. Blurred vision. Enlarged pupils. Unreactive pupils. Blindness. Rapid breathing. Fatigue. Weakness. Seizures.

Information on toxicological effects

Acute toxicity Toxic if inhaled. Toxic in contact with skin. Toxic if swallowed.

Components	Species	Test Results
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Calcitriol (CAS 32222-06-3)

Acute

Oral

LD50	Mouse	0.62 mg/kg
	Rat	1.35 mg/kg

Methyl Alcohol (CAS 67-56-1)

Acute

Oral

LD50	Rat	1187 - 2769 mg/kg
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Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Local effects

Calcitriol	Eye irritancy test Result: Non-irritant. Species: Rabbit
Methyl Alcohol	Eye irritation Result: Non-irritant. Species: Rabbit

Local effects

Calcitriol

Skin irritancy test
 Result: Non-irritant.
 Species: Rabbit

Methyl Alcohol
 Skin irritation
 Result: Non-irritant.
 Species: Rabbit

Respiratory or skin sensitization**Respiratory sensitization**

Knowledge about health hazard is incomplete.

Skin sensitization

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

Methyl Alcohol

Maximisation Test
 Result: Non-sensitizing
 Species: Guinea pig
 Organ: Skin

Calcitriol
 Skin sensitization test
 Result: Non-sensitizing.
 Species: Guinea pig

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Mutagenicity

Methyl Alcohol

Ames test (Salmonella typhimurium)
 Result: Negative (+/- activation)

Calcitriol

In vitro Ames test
 Result: Negative.
 In vivo chromosomal aberration assay in rat bone marrow
 Result: Negative.
 In vivo mouse micronucleus test
 Result: Negative.

Methyl Alcohol

Mutagenicity: Chromosome damage in mice
 Result: Negative
 Mutagenicity: Grasshoppers
 Result: Positive
 Mutagenicity: Yeast
 Result: Positive

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

Methyl Alcohol

10 - 1000 ppm Carcinogenicity
 Result: Not carcinogenic
 Species: Rat
 Organ: Inhalation
 Test Duration: 18 months
 Carcinogenicity: 25mL/twice weekly
 Result: One tumor out of 80 specimens.
 Species: Mouse
 Organ: Dermal
 Test Duration: 50 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Reproductivity

Calcitriol

0.08 - 0.3 microgram/kg Reproductivity and development study
 Result: Teratogenicty.
 Species: Rabbit

0.3 - 0.8 microgram/kg Reproductivity and development study
 Result: Hypercalcemia in offspring.
 Species: Rat

0.3 microgram/kg Reproductivity and development study
 Result: Maternotoxicity and fetotoxicity.
 Species: Rabbit

Reproductivity

Calcitriol

0.3 microgram/kg Reproductivity study

Result: No impairment of fertility or reproductive performance observed.

Species: Rat

0.45 microgram/kg Reproductivity and development study

Result: No teratogenicity noted.

Species: Rat

Methyl Alcohol

20000 ppm Gestational study, Increased incidence of anomalies and maternal effects at high doses.

Species: Rat

Organ: Inhalation

Developmental Toxicity, Behavioral effects in offspring; increased incidence of anomalies; maternal toxicity.

Species: Rat

Gestational study, High doses increased fetal resorptions and malformations, including neural, cranial, and ocular defects.

Species: Mouse

Specific target organ toxicity - single exposure

Causes damage to organs.

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
Methyl Alcohol (CAS 67-56-1)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) > 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) > 100 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

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 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

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
U154: Waste Methyl alcohol

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

UN number	UN1230
UN proper shipping name	Methanol (Methanol/Calcitriol solution)
Transport hazard class(es)	
Class	3
Subsidiary risk	6.1

Packing group II
Packaging non bulk 202
Packaging bulk 242

IATA

UN number UN1230
UN proper shipping name Methanol (Methanol/Calcitriol solution)
Transport hazard class(es)
Class 3
Subsidiary risk 6.1
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



IATA



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.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Methyl Alcohol (CAS 67-56-1) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Flammable (gases, aerosols, liquids, or solids)
Acute toxicity (any route of exposure)
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Methyl Alcohol	67-56-1	99.9

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Methyl Alcohol (CAS 67-56-1)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Contains component(s) regulated under the Safe Drinking Water Act.

US state regulations

California Proposition 65

California Proposition 65 - CRT: Listed date/Developmental toxin

Methyl Alcohol (CAS 67-56-1) Listed: March 16, 2012

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Methyl Alcohol (CAS 67-56-1)

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)	No
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)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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 06-22-2004
Revision date 12-21-2020
Version # 05

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