

SAFETY DATA SHEET

1. Identification

Product Identifier: Calcitriol Injection, USP

Synonyms: (5Z,7E)-9,10-secocholesta-5,7,10(19)-triene-1 α ,3 β ,25-triol 1 α , 25-dihydroxycholecalciferol; Calcitriol.

National Drug Code (NDC): 17478-931-01
17478-932-01

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
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Contact Telephone: 1-800-932-5676

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Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
(5Z,7E)-9,10-secocholesta-5,7,10(19)-triene-1 α ,3 β ,25-triol 1 α , 25-dihydroxycholecalciferol	32222-06-3	Calcitriol	C ₂₇ H ₄₄ O ₃	416.64	0.0001% and 0.0002%

*The formula also contains Dibasic Sodium Phosphate, Anhydrous, 6.7 mg; Edetate Disodium, Dihydrate, 1.1 mg; Monobasic Sodium Phosphate, Monohydrate, 1.8 mg; Polysorbate 20, 4 mg; Sodium Ascorbate, 10 mg; Sodium Chloride, 1.5 mg; and Water for Injection.

4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Hypercalcemia; weakness; headaches; nausea, vomiting; dry mouth; constipation; muscle pain; metallic taste; bone and joint pain; polyuria; polydipsia, anorexia; weight loss, conjunctivitis; pancreatitis; photophobia; runny nose, pruritus; hyperthermia, altered libido; altered liver enzymes; hypercholesterolemia; hypercalcemia,; increased blood pressure; fast heart rate; hyperphosphatemia; hypersensitivity.
Medical Conditions Aggravated by Exposure:	Pre-existing ailments in the following organs: heart, bone, kidney, liver, muscle.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, and metal oxides.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from acids, bases, and oxidizing agents.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Calcitriol	OEL*: 0.1 µg/m ³ , 8 Hour TWA; OEL*: 0.003 µg/m ³ , 8 Hour TWA

* Occupational Exposure Levels (OELs) have been established by private industry.

SDS: Calcitriol Injection, USP

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
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).
Eyes Protection:	Safety glasses with side shields 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.
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 non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color:	Liquid/Colorless to light yellow.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	6.5 – 8.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Acids, bases and oxidizers.

Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: No data available.

Ingestion: May be harmful if swallowed.

Skin Contact: May be harmful if absorbed through the skin. May cause irritation.

Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Calcitriol	Mouse	Oral	LD ₅₀	1.35 mg/kg
Calcitriol	Rat	Oral	LD ₅₀	0.62 mg/kg
Calcitriol	Mouse	Subcutaneous	LD ₅₀	0.066 mg/kg
Calcitriol	Rat	Subcutaneous	LD ₅₀	0.145 mg/kg

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects:

Compound	Study Type	Species	Dose	Effect(s)
Calcitriol anhydrous	Reproductivity test	Rabbit	0.08-0.3 mcg/kg	Increase in birth defects
Calcitriol anhydrous	Reproductivity test	Rat	0.3-0.8 mcg/kg	Hypercalcemia occurred in offspring
Calcitriol anhydrous	Reproductivity test	Rabbit	0.3 mcg/kg	Decreased fetal body weight and number of surviving newborns; maternal effects also occurred
Calcitriol anhydrous	Reproductivity test	Rat	0.45 mcg/kg	No increase in birth defects
Calcitriol anhydrous	Reproductivity test	Rat	3 mcg/kg	Did not impair fertility or reproductive performance

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity:

Compound	Study Type	Cell Type/Organism	Results
Calcitriol Anhydrous	<i>In Vitro</i> Ames assay	Bacteria	Negative
Calcitriol Anhydrous	<i>In Vitro</i> Mammalian chromosomal aberration assay in bone marrow cells	Rat	Negative
Calcitriol Anhydrous	<i>In vivo</i> Micronucleus Test	Mouse	Negative

Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Calcitriol.
Pennsylvania:	Calcitriol.
California Proposition 65:	Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:		HMS Classification:	
Health: 2		Health: 4	
Flammability: 0		Flammability: 0	
Reactivity: 0		Physical Hazard: 0	

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