



SAFETY DATA SHEET

Doxercalciferol Injection

1. IDENTIFICATION

Product Identifier:	Doxercalciferol Injection
Synonyms:	1 α -hydroxyvitamin D, 1 α -OH-D, 1 α - hydroxyergocalciferol.
National Drug Code (NDC):	17478-987-01 17478-987-11 17478-987-21 17478-987-02 17478-987-12 17478-987-22
Recommended Use:	Pharmaceutical. Doxercalciferol Injection is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
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.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Per mL
Doxercalciferol	Doxercalciferol; 1 α -hydroxyvitamin D, 1 α -OH-D, 1 α -hydroxyergocalciferol	54573-75-0	C ₂₈ H ₄₄ O ₂	412.66	2 mcg
Alcohol	Ethyl alcohol	64-17-5	C ₂ H ₅ OH	46.07	5%
Polysorbate 20	Polyoxethylene 20 sorbitan monolaurate	9005-64-5	C ₅₈ H ₁₁₄ O ₂₆ (approximate)	1227.51	10 mg
Sodium Chloride	Sodium chloride	7647-14-5	NaCl	58.44	1.5 mg
Butylated Hydroxytoluene	BHT	128-37-0	C ₁₅ H ₂₄ O	220.35	0.02 mg
Sodium Phosphate Dibasic, Heptahydrate	Disodium hydrogen phosphate heptahydrate Disodium phosphate	7782-85-6	HNa ₂ O ₄ P•7H ₂ O	268.07	14.4 mg
Sodium Phosphate Monobasic, Monohydrate	Sodium dihydrogen phosphate monohydrate Monosodium phosphate	10049-21-5	H ₂ NaO ₄ P•H ₂ O	137.99	1.8 mg
Disodium Edetate	Disodium EDTA dihydrate	6381-92-6	C ₁₀ H ₁₆ N ₂ O ₈ •2H ₂ O•2Na	372.24	1.1 mg

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

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	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:	Signs and symptoms of vitamin D intoxication associated with hypercalcemia include: weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, metallic taste, and anorexia, abdominal pain or stomach ache.
Indication of Immediate Medical Attention and Special Treatment Needed:	The treatment of acute accidental overdosage of Doxercalciferol should consist of general supportive measures. If drug ingestion is discovered within a relatively short time (10 minutes), induction of emesis or gastric lavage may be of benefit in preventing further absorption. If drug ingestion is discovered later than 10 minutes post-ingestion, the administration of mineral oil may promote its fecal elimination.
Medical Conditions Aggravated by Exposure:	Not determined.
Notes to Physician:	Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or foam as necessary.
Unsuitable Extinguishing Media:	Do not use water jet as an extinguisher, as this will spread the fire.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products:	Toxic gases and vapors may be released if involved in a fire.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment and Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

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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:	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 at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light. Store away from oxidizing agents and acids.
Specific End Use:	Pharmaceuticals.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Doxercalciferol	No data available	No data available
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m ³
	NIOSH IDLH	3,300 ppm
	NIOSH REL	1,900 mg/m ³
	ACGIH TWA	1,000 ppm
	ACGIH TLV STEL	1,000 ppm

OSHA PEL: Occupational Safety and Health Administration – Permissible Exposure Limits;
 NIOSH IDLH: National Institute for Occupational Safety and Health – Immediately Dangerous to Life or Health.
 REL: Recommended Exposure Limits.
 ACGIH TWA: American Conference of Governmental Industrial Hygienists – Time Weighted Average.
 TLV: Threshold Limit Value; STEL: Short Term Exposure Limit.

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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 should be worn. 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:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
General Hygiene Considerations:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear colorless solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
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):	Insoluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.

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Decomposition Temperature: No data available.
Viscosity: No data available.

10. STABILITY AND REACTIVITY

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions to Avoid (e.g., static discharge, shock, or vibration): Contact with incompatible materials.

Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition Products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: May cause respiratory irritation.

Ingestion: May cause irritation and malaise.

Skin Contact: Prolonged skin contact may cause temporary 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

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Doxercalciferol	Rat	Oral	LD ₅₀	3.5 mg/kg
Alcohol	Rat	Oral	LD ₅₀	2,404 mg/kg

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Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

May result in cirrhosis of the liver, damage to the heart, and kidneys. May cause increased sensitivity, tolerance, habituation and addiction.

Reproductive Effects:

Pregnancy Category B. There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

It is not known if this product is excreted in human milk. Because many drugs are excreted in human milk and because of the tumorigenicity of this product shown in animal studies, the decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Carcinogenicity:

Not expected to cause cancer.

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.

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12. ECOLOGICAL INFORMATION

Aquatic Toxicity

The product is not classified as environmentally hazardous.

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: 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

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

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15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Doxercalciferol	No
Alcohol	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Doxercalciferol	Not Listed	Not Listed	Not Listed
Alcohol	Listed	Listed	Listed

California Proposition 65:

Alcohol is listed to cause cancer and birth defects or other reproductive harm.

16. OTHER INFORMATION

Not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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