

Doxercalciferol Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Doxercalciferol Injection
Other means of identification : 2 mcg per mL, 50 x 1 mL single dose vials, NDC 55150-357-50
4 mcg per 2 mL, 50 x 2 mL single dose vials, NDC 55150-358-50
4 mcg per 2 mL, 50 x 2 mL multiple dose vials, NDC 55150-359-50

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Flam. Liq. 4 H227

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Signal word (GHS US) : Warning
Hazard statements (GHS US) : H227 - Combustible liquid
Precautionary statements (GHS US) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P370+P378 - In case of fire: Use media other than water to extinguish.
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

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Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	> 99	Not classified
Ethyl alcohol	(CAS-No.) 64-17-5	4 – 6	Flam. Liq. 2, H225 Carc. 1A, H350
Sodium chloride	(CAS-No.) 7647-14-5	< 1	Not classified
Phosphoric acid, monosodium salt, monohydrate	(CAS-No.) 10049-21-5	> 1	Not classified
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS-No.) 6381-92-6	< 1	Not classified
Disodium orthophosphate heptahydrate	(CAS-No.) 7782-85-6	< 1	Not classified
Polyoxyethylene sorbitan monolaurate	(CAS-No.) 9005-64-5	< 1	Not classified
2,6-Di-tert-butyl-p-cresol	(CAS-No.) 128-37-0	< 0.1	Aquatic Chronic 1, H410
Doxercalciferol	(CAS-No.) 54573-75-0	< 0.1	Acute Tox. 1 (Oral), H300

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If not breathing, give artificial respiration.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water. Seek immediate medical attention.
- First-aid measures after ingestion : Wash mouth with water. Do not induce vomiting unless directed by medical personnel. Seek immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after inhalation : May cause irritation if inhaled.
- Symptoms/effects after skin contact : May cause skin irritation.
- Symptoms/effects after eye contact : May cause eye irritation.
- Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Dry chemical, carbon dioxide, water spray or alcohol-resistant foam.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : May form toxic gases during a fire.

5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.
- Methods for cleaning up : Collect spill with suitable absorbent. Dispose in accordance with local, state, and federal requirements.

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6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)		
Not applicable		
Sodium chloride (7647-14-5)		
Not applicable		
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)		
Not applicable		
Phosphoric acid, monosodium salt, monohydrate (10049-21-5)		
Not applicable		
Polyoxyethylene sorbitan monolaurate (9005-64-5)		
Not applicable		
Ethyl alcohol (64-17-5)		
ACGIH	ACGIH OEL STEL [ppm]	1000 ppm
OSHA	OSHA PEL (TWA) [1]	1900 mg/m ³
OSHA	OSHA PEL (TWA) [2]	1000 ppm
IDLH	IDLH [ppm]	3300 ppm (10% LEL)
NIOSH	NIOSH REL (TWA)	1900 mg/m ³
NIOSH	NIOSH REL TWA [ppm]	1000 ppm
2,6-Di-tert-butyl-p-cresol (128-37-0)		
ACGIH	ACGIH OEL TWA	2 mg/m ³ (inhalable fraction and vapor)
NIOSH	NIOSH REL (TWA)	10 mg/m ³
Disodium orthophosphate heptahydrate (7782-85-6)		
Not applicable		
Doxercalciferol (54573-75-0)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use suitable protective gloves to minimize skin contact.
Eye protection : Wear safety glasses or goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : Wear NIOSH approved respirator if workplace exposure limits may be exceeded.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.

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Color	: Colorless
Odor	: Odorless
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	: ≈ 62 °C
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: completely soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Keep away from sources of ignition.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg
Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation - Rat	> 42 g/m ³ (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
Polyoxyethylene sorbitan monolaurate (9005-64-5)	
LD50 oral rat	37000 mg/kg

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Ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LC50 Inhalation - Rat	124.7 mg/l/4h
ATE US (oral)	7060 mg/kg

2,6-Di-tert-butyl-p-cresol (128-37-0)	
LD50 oral rat	> 2930 mg/kg
LD50 dermal rat	> 2000 mg/kg
ATE US (oral)	890 mg/kg

Doxercalciferol (54573-75-0)	
ATE US (oral)	0.5 mg/kg body weight

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans
In OSHA Hazard Communication Carcinogen list	Yes

2,6-Di-tert-butyl-p-cresol (128-37-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	12 – 16 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	9268 – 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [2]	2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Sodium chloride (7647-14-5)	
BCF - Fish [1]	(no bioaccumulation)

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Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32
2,6-Di-tert-butyl-p-cresol (128-37-0)	
BCF - Fish [1]	230 – 2500
Partition coefficient n-octanol/water (Log Pow)	4.17

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Polyoxyethylene sorbitan monolaurate (9005-64-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Ethyl alcohol (64-17-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
2,6-Di-tert-butyl-p-cresol (128-37-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State regulations

Ethyl alcohol (64-17-5)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
Yes	Yes	No	No	

Ethyl alcohol (64-17-5)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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2,6-Di-tert-butyl-p-cresol (128-37-0)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 1 (Oral)	Acute toxicity (oral) Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Carc. 1A	Carcinogenicity Category 1A
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 4	Flammable liquids Category 4
H225	Highly flammable liquid and vapor
H227	Combustible liquid
H300	Fatal if swallowed
H350	May cause cancer
H410	Very toxic to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.