

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 1 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 1. Identification

GHS product identifier : Doxercalciferol Injection
Other means of identification : Doxercalciferol Injection
Product type : Liquid.

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

Product use : Pharmaceuticals (For intended use only.)
Observe technical data sheet/instructions for use.
Specific Treatments: Anti-Parathyroid agent

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

Telephone: 224-443-4617
www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : H227 FLAMMABLE LIQUIDS - Category 4
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H227 - Combustible liquid.
H373 - May cause damage to organs through prolonged or repeated exposure. (liver)

Precautionary statements

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 2 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 2. Hazards identification

Prevention	: P280 - Wear protective gloves, protective clothing and eye or face protection. P210 - Keep away from flames and hot surfaces. No smoking. P260 - Do not breathe vapor.
Response	: P314 - Get medical advice or attention if you feel unwell.
Storage	: P403 + P235 - Store in a well-ventilated place. Keep cool.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Avoid contact with skin and clothing. Wash thoroughly after handling.
Hazards not otherwise classified	: Prolonged or repeated contact may dry skin and cause irritation.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Doxercalciferol Injection

Ingredient name	Other names	%	CAS number
water	-	≥90	7732-18-5
Ethanol	Ethyl alcohol	<10	64-17-5
Sorbitan monolaurate, ethoxylated	-	≤3	9005-64-5
disodium hydrogenorthophosphate	Sodium phosphate dibasic	<1	7558-79-4
Phosphoric acid, monosodium salt, monohydrate	Monobasic Sodium Phosphate, monohydrate	≤0.3	10049-21-5
sodium chloride	Sodium chloride	≤0.3	7647-14-5
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Edetate Disodium	≤0.3	6381-92-6
2,6-di-tert-butyl-p-cresol	Butylated hydroxytoluene	≤0.1	128-37-0
doxercalciferol	-	≤0.1	54573-75-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
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SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 3 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 4. First aid measures

- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention following exposure or if feeling unwell. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Wash skin thoroughly with soap and water or use recognized skin cleanser. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention following exposure or if feeling unwell. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention following exposure or if feeling unwell. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
dryness
cracking
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

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SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 4 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use dry chemical, CO₂, water spray (fog) or foam.

Unsuitable extinguishing media : Do not use water jet.

Specific hazards arising from the chemical : Combustible liquid. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 5 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 6. Accidental release measures

- Large spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not breathe vapor or mist. Do not ingest. Avoid contact with eyes, skin and clothing. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 6 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 8. Exposure controls/personal protection

Ingredient name	Exposure limits
water Ethanol	None. ACGIH TLV (United States, 1/2023). STEL: 1000 ppm 15 minutes. NIOSH REL (United States, 10/2020). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 5/2018). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.
Sorbitan monolaurate, ethoxylated disodium hydrogenorthophosphate Phosphoric acid, monosodium salt, monohydrate sodium chloride Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2) 2,6-di-tert-butyl-p-cresol	None. None. None. None. None. NIOSH REL (United States, 10/2020). TWA: 10 mg/m ³ 10 hours. ACGIH TLV (United States, 1/2023). TWA: 2 mg/m ³ 8 hours. Form: Inhalable fraction and vapor
doxercalciferol	None.

Appropriate engineering controls

- : Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls

- : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

- : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

- : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 7 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 8. Exposure controls/personal protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid. [Clear.]
- Color** : Colorless.
- Odor** : Odorless.
- Odor threshold** : Not available.
- pH** : 7.2 to 7.6
- Melting point** : Not applicable.
- Boiling point, initial boiling point, and boiling range** : Not applicable.
- Flash point** : Closed cup: 61 to 93.3°C (141.8 to 199.9°F)
Open cup: Not applicable.
- Evaporation rate** : Not applicable.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.
- Vapor pressure** : Not applicable.
- Relative vapor density** : Not available.
- Relative density** : 1.0044 [Water = 1]
- Density** : 1.0044 g/cm³ [25°C (77°F)]
- Solubility(ies)** : Not available.
- Partition coefficient: n-octanol/water** : Not applicable.

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 8 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 9. Physical and chemical properties

Auto-ignition temperature : Not applicable.

Decomposition temperature : Not applicable.

SADT : Not available.

Viscosity : Not applicable.

Flow time (ISO 2431) : Not available.

Particle characteristics

Median particle size : Not applicable.

Other information

Physical/chemical properties comments : No additional information.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerization will not occur.

Conditions to avoid : Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.

Incompatible materials : Reactive or incompatible with the following materials:
oxidizing materials

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 9 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 11. Toxicological information

Product/ingredient name	Result	Species	Dose	Exposure
Ethanol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-
Sorbitan monolaurate, ethoxylated	LC50 Inhalation Dusts and mists	Rat - Male, Female	>5.1 mg/l	4 hours
disodium hydrogenorthophosphate	LD50 Dermal	Rat - Male, Female	>2000 mg/kg	-
sodium chloride	LD50 Oral	Rat	17000 mg/kg	-
Glycine, N, N'-1,2-ethanediylbis[N- (carboxymethyl)-, sodium salt, hydrate (1:2:2)	LD50 Oral	Rat	3000 mg/kg	-
	LD50 Oral	Rat	2214.37 mg/kg	-
2,6-di-tert-butyl-p-cresol	LD50 Dermal	Rat - Male, Female	>2000 mg/kg	-
	LD50 Oral	Rat	890 mg/kg	-
doxercalciferol	LD50 Oral	Rat	3500 µg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethanol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.06666667 minutes 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	100 µL	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-
disodium hydrogenorthophosphate	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
sodium chloride	Eyes - Moderate irritant	Rabbit	-	10 mg	-
	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
2,6-di-tert-butyl-p-cresol	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Skin - Moderate irritant	Rabbit	-	48 hours 500 mg	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 10 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 11. Toxicological information

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
2,6-di-tert-butyl-p-cresol	-	3	-

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Ethanol	Category 3	-	Narcotic effects
2,6-di-tert-butyl-p-cresol	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Ethanol	Category 2	-	liver
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Category 2	inhalation	respiratory tract

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : Defatting to the skin. May cause skin dryness and irritation.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : Adverse symptoms may include the following:
irritation
dryness
cracking

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 11 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 11. Toxicological information

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : May cause damage to organs through prolonged or repeated exposure. Prolonged or repeated contact can defat the skin and lead to irritation, cracking and/or dermatitis.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Ethanol	7000	N/A	N/A	124.7	N/A
disodium hydrogenorthophosphate	17000	2500	N/A	N/A	N/A
sodium chloride	3000	N/A	N/A	N/A	N/A
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	2214.37	N/A	N/A	11	N/A
2,6-di-tert-butyl-p-cresol	890	2500	N/A	N/A	N/A
doxercalciferol	3.5	N/A	N/A	N/A	N/A

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 12 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethanol	Acute EC50 17.921 mg/l Marine water Acute EC50 2 mg/l Fresh water Acute LC50 25500 µg/l Marine water Acute LC50 42000 µg/l Fresh water Chronic NOEC 4.995 mg/l Marine water Chronic NOEC 100 ul/L Fresh water Chronic NOEC 0.375 ul/L Fresh water	Algae - <i>Ulva pertusa</i> Daphnia - <i>Daphnia magna</i> Crustaceans - <i>Artemia franciscana</i> - Larvae Fish - <i>Oncorhynchus mykiss</i> Algae - <i>Ulva pertusa</i> Daphnia - <i>Daphnia magna</i> - Neonate Fish - <i>Gambusia holbrooki</i> - Larvae	96 hours 48 hours 48 hours 4 days 96 hours 21 days 12 weeks
Sorbitan monolaurate, ethoxylated disodium hydrogenorthophosphate	Chronic NOEC 10 mg/l Fresh water Acute EC50 >100 mg/l Fresh water Acute LC50 3580000 µg/l Fresh water Acute LC50 >100 mg/l Fresh water Acute NOEC >100 mg/l Fresh water	Daphnia - <i>Daphnia magna</i> Algae - <i>Desmodesmus subspicatus</i> Daphnia - <i>Daphnia magna</i> Fish - <i>Oncorhynchus mykiss</i> Algae - <i>Desmodesmus subspicatus</i>	21 days 72 hours 48 hours 96 hours 72 hours
sodium chloride	Acute NOEC >100 mg/l Fresh water Acute NOEC 100 mg/l Fresh water Acute EC50 2430000 µg/l Fresh water Acute EC50 519.6 mg/l Fresh water Acute EC50 402.6 mg/l Fresh water Acute IC50 6.87 g/L Fresh water Acute LC50 1000000 µg/l Fresh water Chronic LC10 781 mg/l Fresh water Chronic NOEC 6 g/L Fresh water Chronic NOEC 0.314 g/L Fresh water Chronic NOEC 100 mg/l Fresh water Chronic NOEC 25 mg/l Fresh water	Daphnia - <i>Daphnia magna</i> Fish - <i>Oncorhynchus mykiss</i> Algae - <i>Navicula seminulum</i> Crustaceans - <i>Cypris subglobosa</i> Daphnia - <i>Daphnia magna</i> Aquatic plants - <i>Lemna minor</i> Fish - <i>Morone saxatilis</i> - Larvae Crustaceans - <i>Hyalella azteca</i> - Juvenile (Fledgling, Hatchling, Weanling) Aquatic plants - <i>Lemna minor</i> Daphnia - <i>Daphnia pulex</i> Fish - <i>Gambusia holbrooki</i> - Adult Daphnia	48 hours 96 hours 96 hours 48 hours 48 hours 96 hours 96 hours 3 weeks 96 hours 21 days 8 weeks 21 days
Glycine, N,N'-1,2-ethanediybis [N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)			
2,6-di-tert-butyl-p-cresol	Acute EC50 0.48 mg/l Fresh water Chronic NOEC ≥23.8 mg/l Fresh water	Daphnia Fish	48 hours 70 days

Conclusion/Summary : Not available.

Persistence and degradability

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 13 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 12. Ecological information

Product/ingredient name	Test	Result	Dose	Inoculum
Sorbitan monolaurate, ethoxylated	EU 301F Ready Biodegradability - Manometric Respirometry Test	62.5 % - Readily - 28 days	-	Activated sludge
2,6-di-tert-butyl-p-cresol	OECD 309 Aerobic Mineralization in Surface Water - Simulation Biodegradation Test	2 % - Not readily - 28 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Ethanol	-	-	Readily
Sorbitan monolaurate, ethoxylated	-	-	Readily
2,6-di-tert-butyl-p-cresol	-	-	Not readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
water	-1.38	-	Low
Ethanol	-0.35	-	Low
disodium hydrogenorthophosphate	-5.8	-	Low
2,6-di-tert-butyl-p-cresol	5.1	330 to 1800	High

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 14 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 13. Disposal considerations

Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	NA1993	Not regulated.	Not regulated.
UN proper shipping name	Combustible liquid, n.o.s. (Ethanol)	-	-
Transport hazard class(es)	Combustible liquid.	-	-
Packing group	III	-	-
Environmental hazards	No.	No.	No.

Additional information

DOT Classification

: Non-bulk packages (less than or equal to 119 gal) of combustible liquids are not regulated as hazardous materials.

Limited quantity Yes.

Packaging instruction Exceptions: 150. Non-bulk: 203. Bulk: 241.

Quantity limitation Passenger aircraft/rail: 60 L. Cargo aircraft: 220 L.

Special provisions 148, IB3, T1, TP1

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined

United States inventory (TSCA 8b): Not determined.

Clean Water Act (CWA) 311: disodium hydrogenorthophosphate

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 15 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : FLAMMABLE LIQUIDS - Category 4
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2
HNOC - Defatting irritant

Composition/information on ingredients

Name	%	Classification
Ethanol	<10	FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2 HNOC - Defatting irritant EYE IRRITATION - Category 2B
disodium hydrogenorthophosphate	<1	EYE IRRITATION - Category 2B
sodium chloride	≤0.3	EYE IRRITATION - Category 2A
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	≤0.3	ACUTE TOXICITY (inhalation) - Category 4 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2
2,6-di-tert-butyl-p-cresol	≤0.1	ACUTE TOXICITY (oral) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
doxercalciferol	≤0.1	ACUTE TOXICITY (oral) - Category 1

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: ETHYL ALCOHOL

New York : None of the components are listed.

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SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 16 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

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New Jersey : The following components are listed: ETHYL ALCOHOL

Pennsylvania : The following components are listed: ETHANOL

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	*	2
Flammability		2
Physical hazards		0

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National Fire Protection Association (U.S.A.)



Procedure used to derive the classification



Meitheal Pharmaceuticals, Inc.

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SDS Title: Doxercalciferol Injection Safety Data Sheet	SDS Number: SDS-000020	Page Number: Page 17 of 17
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 16. Other information

Classification	Justification
FLAMMABLE LIQUIDS - Category 4 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	On basis of test data Calculation method

History

Date of issue/Date of revision	: 01/05/2024
Date of previous issue	: 01/07/2022
Version	: 3.0
Prepared by	: Sphera Solutions
Key to abbreviations	: ATE = Acute Toxicity Estimate AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) N/A = Not available UN = United Nations

References	: HCS (U.S.A.) - Hazard Communication Standard International transport regulations
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Indicates information that has changed from previously issued version.

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