

Calcitriol

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 02/07/2025 Supersedes version of: 03/04/2023 Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Calcitriol
Chemical name : Calcitriol
EC-No. : 250-963-8
CAS-No. : 32222-06-3
Product code : 201600134

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 1 H300
Acute toxicity (dermal), Category 1 H310
Acute toxicity (inhal.), Category 2 H330
Reproductive toxicity, Category 2 H361
Specific target organ toxicity – Repeated exposure, Category 1 H372
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Danger



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Hazard statements (CLP)	: H300+H310+H330 - Fatal if swallowed, in contact with skin or if inhaled. H361 - Suspected of damaging fertility or the unborn child. H372 - Causes damage to organs through prolonged or repeated exposure.
Precautionary statements (CLP)	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P284 - Wear respiratory protection. P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 - Immediately call a POISON CENTER or doctor. P314 - Get medical advice/attention if you feel unwell. P320 - Specific treatment is urgent (see supplemental first aid instruction on this label). P321 - Specific treatment (see supplemental first aid instruction on this label). P330 - Rinse mouth. P361+P364 - Take off immediately all contaminated clothing and wash it before reuse. P403+P233 - Store in a well-ventilated place. Keep container tightly closed. P405 - Store locked up. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)	:		
		GHS06	GHS08

2.3. Other hazards

Other information	: Active substance (in pharmaceutical products). Warning - substance not yet tested completely.
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SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Calcitriol	CAS-No.: 32222-06-3 EC-No.: 250-963-8	≤ 100	Acute Tox. 1 (Oral), H300 (ATE=0.62 mg/kg bodyweight) Acute Tox. 1 (Dermal), H310 (ATE=50 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE=0.05 mg/l) Repr. 2, H361 STOT RE 1, H372

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
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First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. Immediately call a POISON CENTER/doctor.
First-aid measures after skin contact	: Take off contaminated clothing. Wash skin thoroughly with mild soap and water. Get immediate medical advice/attention.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation	: Fatal if inhaled.
Symptoms/effects after skin contact	: Fatal in contact with skin.
Symptoms/effects after ingestion	: Fatal 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	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
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5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with skin, eyes and clothing.
For non-emergency personnel	
Emergency procedures	: Evacuate unnecessary personnel.
For emergency responders	
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up	: Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Do not expose pregnant or breastfeeding women.
Precautions for safe handling	: Avoid all unnecessary exposure. Ensure good ventilation of the work station.
Hygiene measures	: Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white, almost white.
Appearance	: Crystals.
Molecular mass	: 416.64 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 111 – 115 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable

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Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not 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

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Fatal if swallowed.
Acute toxicity (dermal)	: Fatal in contact with skin.
Acute toxicity (inhalation)	: Fatal if inhaled.

Calcitriol (32222-06-3)	
LD50 oral rat	0.62 mg/kg (RTECS No FZ4645000)
LD50 dermal	> 50 – ≤ 200 mg/kg (estimated value)
LC50 Inhalation - Rat (Dust/Mist)	> 0.05 – ≤ 0.5 mg/l/4h (estimated value)

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Inconclusive data)

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Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Lack of data)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Lack of data)

12.2. Persistence and degradability

Calcitriol (32222-06-3)

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information




In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 2811	UN 2811	UN 2811
14.2. UN proper shipping name		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.

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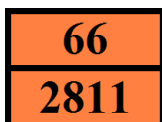
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
Transport document description		
UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, I, (C/E)	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, I	UN 2811 Toxic solid, organic, n.o.s., 6.1, I
14.3. Transport hazard class(es)		
6.1	6.1	6.1
		
14.4. Packing group		
I	I	I
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-A	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: T2
Special provisions (ADR)	: 274, 614
Limited quantities (ADR)	: 0
Excepted quantities (ADR)	: E5
Packing instructions (ADR)	: P002, IBC07
Mixed packing provisions (ADR)	: MP18
Portable tank and bulk container instructions (ADR)	: T6
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: S10AH, L10CH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 1
Special provisions for carriage - Packages (ADR)	: V10
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV1, CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9, S14
Hazard identification number (Kemler No.)	: 66
Orange plates	:



Tunnel restriction code (ADR)	: C/E
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Transport by sea

Special provisions (IMDG)	: 274
Limited quantities (IMDG)	: 0
Excepted quantities (IMDG)	: E5
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC99
Tank instructions (IMDG)	: T6
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: B
Properties and observations (IMDG)	: Toxic if swallowed, by skin contact or by inhalation.

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Air transport

PCA Excepted quantities (IATA)	: E5
PCA Limited quantities (IATA)	: Forbidden
PCA limited quantity max net quantity (IATA)	: Forbidden
PCA packing instructions (IATA)	: 666
PCA max net quantity (IATA)	: 5kg
CAO packing instructions (IATA)	: 673
CAO max net quantity (IATA)	: 50kg
Special provisions (IATA)	: A3, A5
ERG code (IATA)	: 6L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

Classification of the substance or mixture.

Indication of changes		
Section	Changed item	Comments
	UN-No. (RID)	Added
	Number of blue cones/lights (ADN)	Added
	Equipment required (ADN)	Added
	Excepted quantities (ADN)	Added

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Indication of changes		
Section	Changed item	Comments
	Limited quantities (ADN)	Added
	Danger labels (ADN)	Added
	Classification code (ADN)	Added
	Proper Shipping Name (RID)	Added
	Hazard identification number (RID)	Added
	Special provisions for carriage - Loading, unloading and handling (RID)	Added
	Special provisions for carriage – Packages (RID)	Added
	Transport category (RID)	Added
	Special provisions for RID tanks (RID)	Added
	Tank codes for RID tanks (RID)	Added
	Portable tank and bulk container special provisions (RID)	Added
	Portable tank and bulk container instructions (RID)	Added
	Mixed packing provisions (RID)	Added
	Packing instructions (RID)	Added
	Excepted quantities (RID)	Added
	Limited quantities (RID)	Added
	Special provisions (RID)	Added
	Packing group (RID)	Added
	Classification code (RID)	Added
	IBC special provisions (IMDG)	Removed
	CAO max net quantity (IATA)	Modified
	CAO packing instructions (IATA)	Modified
	PCA max net quantity (IATA)	Modified
	PCA packing instructions (IATA)	Modified
	PCA limited quantity max net quantity (IATA)	Modified
	PCA Limited quantities (IATA)	Modified
	PCA Excepted quantities (IATA)	Modified
	Special packing provisions (ADR)	Removed
	Limited quantities (IMDG)	Modified
	Tank instructions (IMDG)	Modified
	IBC packing instructions (IMDG)	Modified
	Excepted quantities (IMDG)	Modified
	Special provisions for carriage - Operation (ADR)	Modified
	Special provisions for carriage - Loading, unloading and handling (ADR)	Modified

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Indication of changes		
Section	Changed item	Comments
	Special provisions for carriage - Packages (ADR)	Modified
	Tank code (ADR)	Modified
	Portable tank and bulk container instructions (ADR)	Modified
	Mixed packing provisions (ADR)	Modified
	Packing instructions (ADR)	Modified
	Supersedes version of	Added
	Revision date	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.1	Synonyms	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Precautionary statements (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after inhalation	Modified
4.2	Symptoms/effects after skin contact	Modified
4.2	Symptoms/effects after ingestion	Modified
4.2	Symptoms/effects after eye contact	Removed
4.2	Symptoms/effects	Removed
4.3	Other medical advice or treatment	Removed
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified

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Indication of changes		
Section	Changed item	Comments
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.1	General measures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Modified
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.2	Storage conditions	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.3	Specific end uses	Removed
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Eye protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Molecular mass	Added
9	Colour	Added
9	Appearance	Modified
9	Melting point	Added
9	Odour	Removed
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	ATE CLP (dust,mist)	Modified
11.1	LD50 dermal	Added
11.1	ATE CLP (vapours)	Removed
11.1	ATE CLP (gases)	Removed
11.1	ATE CLP (dermal)	Modified
11.1	ATE CLP (oral)	Modified
11.1	LD50 oral rat	Modified
12.1	LC50 Inhalation - Rat (Dust/Mist)	Added
12.1	Ecology - general	Removed
13.1	Product/Packaging disposal recommendations	Removed

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Indication of changes		
Section	Changed item	Comments
13.1	Regional waste regulation	Removed
14.1	UN-No. (ADN)	Added
14.2	Proper Shipping Name (ADN)	Added
14.3	Danger labels (RID)	Added
14.4	Packing group (ADN)	Added
14.4	Packing group (IATA)	Modified
14.4	Packing group (IMDG)	Modified
14.4	Packing group (ADR)	Modified
14.6	Special provisions (ADN)	Added
14.6	Transport category (ADR)	Modified
14.6	Excepted quantities (ADR)	Modified
14.6	Limited quantities (ADR)	Modified
14.6	Tunnel restriction code (ADR)	Modified
14.6	Hazard identification number (Kemler No.)	Modified

Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Oral)	Acute toxicity (oral), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
Repr. 2	Reproductive toxicity, Category 2
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

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