Iris Biotech GmbH



## **Safety Data Sheet**

according to Regulation (EC) No 1907/2006

## 1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6)

Revision date: 16.05.2023 Product code: LS-3790 Page 1 of 11

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

#### 1.1. Product identifier

1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6)

### Further trade names

Ercalcitriol-d6

1-alpha,25-Dihydroxy-Vitamin D2-d6

(5Z,7E,22E)-(1S,3R)-9,10-seco-5,7,10(19),22-ergostatetraen-1,3,25-triol-d6 (1R,3S,Z)-5-((E)-2-((7aR)-1-((2R,5S,E)-7,7,7-trideutero-6-(trideuteromethyl)

-6-hydroxy-5-methylhept-3-en-2-yl)-7a-methyldihydro-1H-inden-4(2H,5H,6H,7H,7aH)-ylidene)ethyliden

(1R,3S,Z)-5-(2-((7aR,E)-1-((2R,5S,E)-6-hydroxy-5-methyl-6-(methyl-d3)hept-3-en-2-yl-7,7,7-d3)

-7a-methyloctahydro-4H-inden-4-ylidene)ethylidene)-4-methylenecyclohexane-1,3-diol

Substance name: 1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6)

CAS No: 216244-04-1

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

#### Use of the substance/mixture

Laboratory chemical. Manufacture of the substance.

### Uses advised against

Do not use for private purposes (household). Restrictions on use: Pharmaceutical substance

### 1.3. Details of the supplier of the safety data sheet

Company name: Iris Biotech GmbH

Street: Adalbert-Zoellner-Straße 1
Place: D-95615 Marktredwitz, Germany

Post-office box: 568

D-95605 Marktredwitz, Germany

Telephone: +49 9231 97121 0 Telefax: +49 9231 97121 99

e-mail: info@iris-biotech.de

Contact person: Compliance Department Telephone: +49 9231 97121 0

e-mail: sds@iris-biotech.de
Internet: www.iris-biotech.de

Responsible Department: Only available during office hours.

**1.4. Emergency telephone** +49 (0)89 19240 (POISON CENTER Munich: 24 h)

number:

### **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

### Regulation (EC) No 1272/2008

Acute Tox. 2; H330 Acute Tox. 3; H311 Acute Tox. 3; H301 STOT RE 1: H372

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

# Regulation (EC) No 1272/2008

Signal word: Danger



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### Pictograms:





#### **Hazard statements**

H301+H311 Toxic if swallowed or in contact with skin.

H330 Fatal if inhaled.

H372 Causes damage to organs through prolonged or repeated exposure.

#### **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing

protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P403+P233 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/container to an approved disposal site.

### Additional advice on labelling

Warning - substance not yet tested completely.

### 2.3. Other hazards

Product is not dust explosive in its original delivery form. The addition of particulate matter, however, results in a dust explosion risk.

### **SECTION 3: Composition/information on ingredients**

### 3.1. Substances

### **Chemical characterization**

(1R,3S,Z)-5-(2-((7aR,E)-1-((2R,5S,E)-6-hydroxy-5-methyl-6-(methyl-d3)hept-3-en-2-yl-7,7,7-d3)

 $\hbox{-}7a-methyloctahydro-4H-inden-4-ylidene) ethylidene)-4-methylenecyclohexane-1, 3-diologia was also beta and a simple of the properties of the properties$ 

### **Hazardous components**

CAS No	Chemical name			
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
216244-04-1	1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6)			100 %
	Acute Tox. 2, Acute Tox. 3, Acute T	ox. 3, STOT RE 1; H330 H311 H30	1 H372	

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

#### Specific Conc. Limits. M-factors and ATE

CAS No	EC No	Chemical name	Quantity		
	Specific Conc. Limits, M-factors and ATE				
216244-04-1		1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6)	100 %		
	inhalation: ATE = 0,5 mg/l (vapours); inhalation: ATE = 0,05 mg/l (dusts or mists); dermal: ATE = 300 mg/kg; oral: ATE = 100 mg/kg				

## **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

#### **General information**

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

In all cases of doubt, or when symptoms persist, seek medical advice.





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### After inhalation

Provide fresh air. No mouth-to-mouth or mouth-to-nose resuscitation. Use Ambu bag or ventilator. Call a physician immediately. Remove casualty to fresh air and keep warm and at rest. In case of irregular breathing or respiratory arrest provide artificial respiration.

#### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Call a physician immediately. After contact with skin, wash immediately with plenty of water and soap.

### After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist. If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

#### After ingestion

Induce vomiting when the affected person is not unconscious. Call a physician immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person or a person with cramps.

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

No information available.

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

Treat symptomatically.

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

# Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Water spray. alcohol resistant foam. Dry extinguishing powder. Sand.

### Unsuitable extinguishing media

High power water jet.

### 5.2. Special hazards arising from the substance or mixture

Non-flammable. Thermal decomposition can lead to the escape of irritating gases and vapours. In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide (CO).

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Usual measures for fire prevention.

# **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

### General advice

Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment. Provide adequate ventilation.

In case of fire: Evacuate area.

### For non-emergency personnel

Take up carefully when dry.

### For emergency responders

Take up mechanically, placing in appropriate containers for disposal. Take up dust-free and set down dust-free.

## 6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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### 6.3. Methods and material for containment and cleaning up

#### For containment

Avoid dust formation.

### For cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Take up mechanically.

#### Other information

Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation.

Clear contaminated areas thoroughly.

## 6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

Treat the recovered material as prescribed in the section on waste disposal.

### **SECTION 7: Handling and storage**

### 7.1. Precautions for safe handling

#### Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust. Provide adequate ventilation.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid contact with skin, eyes and clothes.

### Advice on protection against fire and explosion

Usual measures for fire prevention.

### Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

Provide adequate ventilation.

# Further information on handling

Handle under dry argon.

## 7.2. Conditions for safe storage, including any incompatibilities

# Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only.

Provide adequate ventilation as well as local exhaustion at critical locations.

Handle and store contents under inert gas. Protect from moisture.

storage temperature: -20 °C

#### Hints on joint storage

Only substances of the same storage class are stored together.

# Further information on storage conditions

Protect from light!

Sensitive to air Keep under argon.

#### 7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

# **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters





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#### Additional advice on limit values

To date, no national critical limit values exist.

#### 8.2. Exposure controls





#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

# Individual protection measures, such as personal protective equipment

### Eye/face protection

Wear eye/face protection.

Tightly fitting safety goggles. Face shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Wear suitable gloves.

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

## Skin protection

Use of protective clothing.

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### Thermal hazards

No data available

### **Environmental exposure controls**

Discharge into the environment must be avoided.

### **SECTION 9: Physical and chemical properties**

### 9.1. Information on basic physical and chemical properties

Physical state: solid

Colour: white/ whitish
Odour: No data available
Odour threshold: not determined

Melting point/freezing point: not determined





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Boiling point or initial boiling point and not determined

boiling range:

Flammability: not determined Lower explosion limits: No data available No data available Upper explosion limits: No data available Flash point: Auto-ignition temperature: No data available Decomposition temperature: No data available pH-Value: No data available Viscosity / kinematic: not applicable Water solubility: No data available

Solubility in other solvents

not determined

No data available Dissolution rate: No data available Partition coefficient n-octanol/water: Dispersion stability: No data available Vapour pressure: No data available Density: No data available Relative density: No data available Bulk density: No data available No data available Relative vapour density: Particle characteristics: No data available

### 9.2. Other information

# Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive. Product is not dust explosive in its original delivery form. The addition of particulate matter, however, results in a dust explosion risk.

Sustaining combustion: No data available

Self-ignition temperature

Solid: No data available

Oxidizing properties

No data available

### Other safety characteristics

Evaporation rate: not determined Solvent content: No data available Solid content: not determined Viscosity / dynamic: not applicable Flow time: not applicable

# **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

No data available

# 10.2. Chemical stability

Stable under recommended storage conditions.

Sensitive to air Keep under argon.

# 10.3. Possibility of hazardous reactions

No data available

### 10.4. Conditions to avoid

Protect from moisture.

Keep away from heat.

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Protect from light! Sensitive to air

### 10.5. Incompatible materials

Oxidizing agents, strong.

Oxygen, Contact with air/oxygen

### 10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours. In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide (CO).

#### **Further information**

In case of fire: See chapter 5.

### **SECTION 11: Toxicological information**

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

## Toxicocinetics, metabolism and distribution

No data available

### **Acute toxicity**

Fatal if inhaled.

Toxic if swallowed.

Toxic in contact with skin.

CAS No	Chemical name							
	Exposure route	Dose		Species	Source	Method		
216244-04-1	1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6)							
	oral	ATE 10 mg/kg	00					
	dermal	ATE 30 mg/kg	00					
	inhalation vapour	ATE 0,	5 mg/l					
	inhalation dust/mist	ATE 0,	05 mg/l					

## Irritation and corrosivity

Based on available data, the classification criteria are not met.

### Sensitising effects

Based on available data, the classification criteria are not met.

### Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

### STOT-single exposure

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure. (1-alpha,25-Dihydroxy-Vitamin D2-(26,26,26,27,27,27-d6))

### **Aspiration hazard**

Based on available data, the classification criteria are not met.

### Specific effects in experiment on an animal

No data available

#### **Practical experience**

No data available

## 11.2. Information on other hazards





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### **Endocrine disrupting properties**

No data available

#### **Further information**

RTECS: No data available

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly

investigated. Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

## **SECTION 12: Ecological information**

### 12.1. Toxicity

Based on available data, the classification criteria are not met.

### 12.2. Persistence and degradability

No data available

## 12.3. Bioaccumulative potential

No data available

### 12.4. Mobility in soil

No data available

### 12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms.

### 12.7. Other adverse effects

Warning - substance not yet tested completely.

### **Further information**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

Discharge into the environment must be avoided.

### **SECTION 13: Disposal considerations**

# 13.1. Waste treatment methods

## **Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Consult the appropriate local waste disposal expert about waste disposal.

Handle contaminated packages in the same way as the substance itself.

# Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

# **SECTION 14: Transport information**

### Land transport (ADR/RID)

14.1. UN number or ID number: UN 2811

14.2. UN proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (1-alpha,25-Dihydroxy-Vitamin D2-

(26,26,26,27,27,27-d6))

14.3. Transport hazard class(es):6.114.4. Packing group:IIHazard label:6.1



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Classification code: T2
Special Provisions: 274 614
Limited quantity: 500 g
Excepted quantity: E4
Transport category: 2
Hazard No: 60
Tunnel restriction code: D/E

Inland waterways transport (ADN)

14.1. UN number or ID number: UN 2811

14.2. UN proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (1-alpha,25-Dihydroxy-Vitamin D2-

(26,26,26,27,27,27-d6))

14.3. Transport hazard class(es):6.114.4. Packing group:IIHazard label:6.1



Classification code: T2

Special Provisions: 274 614 802
Limited quantity: 500 g
Excepted quantity: E4

Marine transport (IMDG)

14.1. UN number or ID number: UN 2811

14.2. UN proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (1-alpha,25-Dihydroxy-Vitamin D2-

(26,26,26,27,27,27-d6))

 14.3. Transport hazard class(es):
 6.1

 14.4. Packing group:
 II

 Hazard label:
 6.1



Special Provisions: 274
Limited quantity: 500 g
Excepted quantity: E4
EmS: F-A, S-A

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: UN 2811

14.2. UN proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (1-alpha,25-Dihydroxy-Vitamin D2-

(26,26,26,27,27,27-d6))

14.3. Transport hazard class(es):6.114.4. Packing group:IIHazard label:6.1



Special Provisions:

Limited quantity Passenger:

1 kg

Passenger LQ:

Y644





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Excepted quantity: E4

IATA-packing instructions - Passenger:669IATA-max. quantity - Passenger:25 kgIATA-packing instructions - Cargo:676IATA-max. quantity - Cargo:100 kg

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

Warning: Acute Toxicity.

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** regulatory information

Information according to 2012/18/EU

**H2 ACUTE TOXIC** 

(SEVESO III):

#### **Additional information**

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

### **National regulatory information**

Employment restrictions: Observe restrictions to employment for juveniles according to the

'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for

expectant or nursing mothers.

3 - highly hazardous to water

Water hazard class (D): 3 - highly hazardous to water
Skin resorption/Sensitization: Permeates easily through outer skin and causes poisoning.

# 15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

### **SECTION 16: Other information**

## Abbreviations and acronyms

ADR: Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road).

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

**UN: United Nations** 

CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate





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LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

EmS: Emergency Schedules
MFAG: Medical First Aid Guide

IATA: International Air Transport Association ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at http://abbrev.esdscom.eu

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

### Relevant H and EUH statements (number and full text)

H301 Toxic if swallowed.

H301+H311 Toxic if swallowed or in contact with skin.

H311 Toxic in contact with skin.

H330 Fatal if inhaled.

H372 Causes damage to organs through prolonged or repeated exposure.

#### **Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.