

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Vitamin D2-(6,19,19-d3)

Revision date: 19.01.2022

Product code: LS-3800

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Vitamin D2-(6,19,19-d3)

Further trade names

Ergocalciferol-d3

Calciferol-(6,19,19-d3)

ErcalcioI-(6,19,19-d3)

Deuterated vitamin D2

Irradiated ergosterol-(6,19,19-d3)

(5Z,7E,22E)-(3S)-9,10-seco-5,7,10(19),22-ergostatetraen-3-ol-d3

(1S,E)-4-(dideuteromethylene)-3-((E)-2-((7aR)-1-((2R,5R,E)-5,6-dimethylhept-3-en-2-yl)

-7a-methyldihydro-1H-inden-4(2H,5H,6H,7H,7aH)-ylidene)-1-deuteroethylidene)cyclohexanol

(1S,3Z)-4-(Methylene-d2)-3-[(2E)-2-[(1R,3aS,7aR)-octahydro-7a-methyl-1-[(1R,2E,4R)

-1,4,5-trimethyl-2-hexen-1-yl]-4H-inden-4-ylidene]ethylidene-1-d]cyclohexanol

Substance name: Vitamin D2-(6,19,19-d3)

CAS No: 1217448-46-8

EC No: 690-543-5

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 sheetCompany 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 number: +49 (0)89 19240 (POISON CENTER Munich: 24 h)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Acute toxicity: Acute Tox. 2

Acute toxicity: Acute Tox. 3

Acute toxicity: Acute Tox. 3

Specific target organ toxicity - repeated exposure: STOT RE 1

Hazard Statements:

Fatal if inhaled.

Toxic in contact with skin.

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Toxic if swallowed.
 Causes damage to organs through prolonged or repeated exposure.

2.2. Label elements
Regulation (EC) No. 1272/2008
Signal word: Danger

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

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/doctor.
 P330 Rinse mouth.
 P302+P352 IF ON SKIN: Wash with plenty of Water.
 P312 Call a POISON CENTER/doctor if you feel unwell.
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P310 Immediately call a POISON CENTER/doctor.
 P314 Get medical advice/attention if you feel unwell.

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

(5Z,7E,22E)-(3S)-9,10-seco-5,7,10(19),22-ergostatetraen-3-ol-d3, (1S,E)-4-(dideuteromethylene)-3-((E)-2-((7aR)-1-((2R,5R,E)-5,6-dimethylhept-3-en-2-yl)-7a-methyldihydro-1H-inden-4(2H,5H,6H,7H,7aH)-ylidene)-1-deuteroethylidene)cyclohexanol

 Sum formula: C₂₈H₄₁D₃O

Molecular weight: 399,67 g/mol

Hazardous components

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	GHS Classification	
1217448-46-8	Vitamin D2-(6,19,19-d3)	100 %
	690-543-5	
	Acute Tox. 2, Acute Tox. 3, Acute Tox. 3, STOT RE 1; H330 H311 H301 H372	

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

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Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
1217448-46-8	690-543-5	Vitamin D2-(6,19,19-d3)	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.

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

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). Nitrogen oxides (NO_x).

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.

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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**

Provide adequate ventilation. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment. Provide adequate ventilation. Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid contact with skin, eyes and clothes.

Wear personal protection equipment.

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.

6.3. Methods and material for containment and cleaning up**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. Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. Provide adequate ventilation.

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. Keep container tightly closed in a

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cool, well-ventilated place. Keep under argon.
Handle and store contents under inert gas. Protect from moisture.
storage temperature: -20 °C

Hints on joint storage

No special measures are necessary.

Further information on storage conditions

Keep under argon.
Sensitive to air
Protect from light!

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****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

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respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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

Changes in the physical state

Melting point/freezing point:	114 - 118 °C
Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Flash point:	No data available

Flammability

Solid/liquid:	not determined
Gas:	not applicable

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.

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value:	not determined
Viscosity / dynamic:	not applicable
Viscosity / kinematic:	not applicable
Flow time:	not applicable
Water solubility:	No data available

Solubility in other solvents

not determined

Dissolution rate:	not determined
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Bulk density:	not determined
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes**

Sustaining combustion:	No data available
Oxidizing properties	
No data available	

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Other safety characteristics

Solvent content: No data available
 Solid content: not determined
 Evaporation rate: not determined

Further Information
SECTION 10: Stability and reactivity
10.1. Reactivity

No data available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Protect from moisture.
 Keep away from heat.
 Sensitive to air
 Protect from light!

10.5. Incompatible materials

Oxidizing agents, strong.

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). Nitrogen oxides (NO_x).

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
Toxicokinetics, metabolism and distribution

No data available

Acute toxicity

Fatal if inhaled.
 Toxic if swallowed.
 Toxic in contact with skin.
 Classified according to Regulation (EU) 1272/2008, Annex VI (Table 3.1/3.2). (Index No. 603-179-00-9).

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
1217448-46-8	Vitamin D2-(6,19,19-d3)				
	oral	ATE 100 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 0,5 mg/l			
	inhalation aerosol	ATE 0,05 mg/l			

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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. (Vitamin D2-(6,19,19-d3))

Classified according to Regulation (EU) 1272/2008, Annex VI (Table 3.1/3.2). (Index No. 603-179-00-9).

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**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**

No data available

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

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6. Endocrine disrupting properties

No data available

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

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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. (Vitamin D2 (6,19,19-d3))
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	II
Hazard label:	6.1 
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. (Vitamin D2 (6,19,19-d3))
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	II
Hazard 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. (Vitamin D2 (6,19,19-d3))
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	II
Hazard label:	6.1

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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. (Vitamin D2 (6,19,19-d3))
14.3. Transport hazard class(es): 6.1
14.4. Packing group: II
 Hazard label: 6.1



Special Provisions: A3 A5
 Limited quantity Passenger: 1 kg
 Passenger LQ: Y644
 Excepted quantity: E4
 IATA-packing instructions - Passenger: 669
 IATA-max. quantity - Passenger: 25 kg
 IATA-packing instructions - Cargo: 676
 IATA-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 (SEVESO III): H2 ACUTE TOXIC

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.

Water hazard class (D): 2 - obviously 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.

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SECTION 16: Other information**Abbreviations and acronyms**

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

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.