

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

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|-----|----------------|---|
| 1.1 | Product name | DIASOURCE 1,25(OH) ₂ -VIT.D-RIA-CT kit |
| | Catalog # | KIP1929 |
| | Kit components | Anti 1,25(OH) ₂ -Vitamin.D coated tubes
Calibrators 1 to 5
¹²⁵ I 1,25(OH) ₂ -Vitamin.D
Bond Elut Silica Cartridges
Controls 1 and 2
Reconstitution Solution
Elution Solution
Washing Solution |
| 1.2 | Intended Use | In vitro diagnostic use |
| 1.3 | Company | DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
e-mail: tech.support@diasource.be |
| 1.4 | In emergencies | Call your local emergency centre |

2. HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture:****2.1.1 Classification according to Regulation (EC) no 1272/2008 (CLP)****Elution Solution**

Aquatic acute cat. 1 – Aquatic chronic cat. 4

Flammable cat. 2, STOT SE 1, Acute toxicity 3

2.1.2 Additional Information

Classification according to radioprotection regulations.

¹²⁵I 1,25(OH)₂-Vitamin.D

Contains radioactive material

2.2 Label elements:

2.2.1 Labeling according to Regulation (EC) no 1272/2008 (CLP)

Elution Solution


Danger

 H225-H301+311+331-H370-H413
 P210-P233-P280-P302+352-P304+340-P308+310-
 P403+235
 P273-P391-P501

2.2.2 Labeling according to radioprotection regulations

¹²⁵I 1,25(OH)₂-Vitamin.D

2.3 Other hazards:

¹²⁵ I 1,25(OH) ₂ -Vitamin.D	Contains material from bovine origin Tracer: 75 kBq
Elution Solution	Contains material from bovine origin
Reconstitution Solution	Contains material from bovine origin
Controls 1 and 2	Contains material from human origin
Calibrators 1 to 5	Contains material from bovine origin

Although these human materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

3. COMPOSITION/INFORMATION ON INGREDIENTS
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Hazardous ingredients:

Component	Classification	concentration
Reconstitution Solution containing:		
Sodium azide		
CAS-No. 26628-22-8	Aquatic Acute 1- Aquatic chronic 4, H413 T+, N; R28, R50-53	< 0.05%
EC-No. 247-852-1		
Index-No. 011-004-00-7		

Elution Solution containing:			
Sodium azide			
CAS-No.	26628-22-8	Aquatic Acute 1- Aquatic chronic 4, H413	< 0.05%
EC-No.	247-852-1	T+, N; R28, R50-53	
Index-No.	011-004-00-7		
Methanol			
CAS-No.	67-56-1	Flam. Liq. 2, Acute Tox. 3, STOT SE1	< 45%
EC-No.	200-659-6	F; R11 T; R23/24/25-39/23/24/25	
Index-No.	603-001-00-X		

4. FIRST AID MEASURES

4.1 Description of first aid measures

All Kit Components

- After skin contact:*
- Wash immediately with soap and plenty of water for at least 10 minutes.
 - Consult a physician in case of inflammation.
 - In the case of a wound or cut rinse with plenty of water, then dress the wound.
 - Remove contaminated clothing
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes.
 - Consult immediately a physician
- After ingestion:*
- Let drink a lot of water.
 - Consult immediately a physician if ingested in large quantities or if any complaints
- After inhalation:*
- Transfer the person to an open place.
 - If he does not breathe, proceed to artificial respiration or provide oxygen.
 - Consult a physician.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.



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5. FIRE FIGHTING MEASURES

Elution Solution

Suitable extinguishing media:

- Dry chemical powder, water spray, foam, carbon dioxide

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- Vapor may travel considerable distance to source of ignition and flash back.

- Container explosion may occur under fire conditions.

- Emits toxic fumes under fire conditions.

Instructions:

- Due to small quantities: no special instructions apply

Special protective equipment for firefighters:

- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

All Other Kit Components

Suitable extinguishing media:

- Powder, water, carbon dioxide, dry sand

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- No generation of hazardous or toxic gases in dangerous quantities

Instructions:

- Due to small quantities: no special instructions apply

Special protective equipment for firefighters:

- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Elution Solution

Personal protection: see 7

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- Cover with dry-lime, sand, or soda ash.
- Place in covered containers using non-sparking tools and transport outdoors.
- Ventilate area and wash spill site after material pickup is complete
- Evacuate area
- Shut off all sources of ignition

All Other Kit Components

Personal protection: see 8

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- The radioactive material should be wiped up immediately.
- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling



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7. HANDLING AND STORAGE

Elution Solution

Handling

- Use non-sparking tools
- Wash thoroughly after handling
- Wash contaminated clothing before reuse.
- Avoid breathing vapor.
- Avoid contact with eyes, skin and clothing.
- Avoid prolonged and repeated exposure
- NIOSH/MSHA-approved respirator
- Compatible chemical-resistant gloves
- Chemical safety goggles

Storage

- Keep container closed
- Keep away from heat, sparks and open flame
- Store in a cool dry place

All Other Kit Components

Handling:

- Handle radioactive material according to radioprotection rules
- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

Storage:

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Component	No. Value	mg/m ³
Sodium azide CAS 26628-22-8	TLV-TWA	-
	TLV-STEL	-
	TLV-Ceiling	0.29
	OES-LTEL	-
	OES-STEL	0.3
	MAK	0.2
	TRK	
	MAC-TGG 8h	
	MAC-TGG 15min	
	MAC-Ceiling	0.3

	VMA 8h	-
	VMA 15min	0.3
	GWBB 8h	-
	GWBB 15min	-
	Momentary value	0.29
	EC	0.1
	EC-STEL	0.3

Component	Country	Basis	Type	Value mg/m ³	Value (ppm)	Remarks
Methanol CAS 67-56-1	Poland		NDS	100	-	-
	Poland		NDSch	300	-	-
	Poland		NDSP	-	-	-
	Denmark	OEL	TWA	260	200	H
	Germany	TRGS 900	OEL	260	200	4 , H
	Norway	OEL	TWA	130	100	H
	Sweden		LLV	250	200	H
	Switzerland	OEL	OEL	260	200	H M C
	United Kingdom	OEL	OEL	266	200	Skin Indicative limit value
	United Kingdom	OEL	STEL	333	250	Skin Indicative limit value

8.2 Exposure Controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protection equipment

Elution Solution

See 7.

All Other Kit Components

- Eye protection:*
- Safety goggles (¹²⁵I 1,25(OH)₂-Vitamin.D)
 - Face shield (Other components)
- Hand protection:*
- Gloves
- Suitable materials:*
- No data available
- Skin protection:*
- Protective clothing

Operators handling radioactive material should be monitored according to local regulations regarding occupational medicine.

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties****I¹²⁵**

Half-life : 59.9 days

Specific activity : 6.4 x 10¹⁴ Bq.g⁻¹**Coated Tubes:** Tubes**Bond Elut Silica Cartridges :** Cartridges**Controls 1 and 2, Calibrators 1 to 5, ¹²⁵I 1,25(OH)₂-Vitamin.D :** Lyophilized**Other components:** Liquid**9.2 Other Information**

No data available

10. STABILITY AND REACTIVITY**All Kit Components***Stability:* All components are stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities*Conditions/Materials to avoid:* Keep away from metals and acids (Azide containing components)**11. TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects****I¹²⁵ labeled component(s):**

Chronic and acute effects

Radioactivity related adverse effects are only observed at exposure levels that are very much higher than those experienced with the reagents in this kit.

Sodium azide:

Acute oral toxicity

LD50 rat: 27 mg/kg (RTECS)

Absorption symptoms:

Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

Acute inhalation toxicity

Symptoms: Irritation symptoms in the respiratory tract., Inhalation may lead to the formation of oedemas in the respiratory tract., Symptoms may be delayed.

Acute dermal toxicity

LD50 rabbit: 20 mg/kg (RTECS) (Regulation (EC) No 1272/2008, Annex VI)

Skin irritation

Possible damages: slight irritation

Eye irritation

Possible damages: slight irritation

Sensitisation

This information is not available.

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.



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Reproductive toxicity	This information is not available.
Teratogenicity	This information is not available.
Specific target organ toxicity - single exposure	This information is not available.
Specific target organ toxicity - repeated exposure	This information is not available.
Aspiration hazard	This information is not available.
Methanol:	
Acute oral toxicity	LDLO human: 143 mg/kg (RTECS) LD50 rat: 5,628 mg/kg (IUCLID) Absorption symptoms: Nausea, Vomiting
Acute inhalation toxicity	LC50 rat: 85.26 mg/l; 4 h (IUCLID) Absorption symptoms: Irritation symptoms in the respiratory tract.
Acute dermal toxicity	LD50 rabbit: ca. 17,100 mg/kg (External MSDS)
Skin irritation	Drying-out effect resulting in rough and chapped skin.
Eye irritation	Irritations of mucous membranes
Sensitisation	Sensitisation test: guinea pig Result: negative (IUCLID)
Germ cell mutagenicity	Genotoxicity in vivo Mutagenicity (mammal cell test): micronucleus. Result: negative (IUCLID)
Genotoxicity in vitro	Ames test Result: negative (IUCLID)
Carcinogenicity	This information is not available.
Reproductive toxicity	This information is not available.
Teratogenicity	This information is not available.
CMR effects	Carcinogenicity: Did not show carcinogenic effects in animal experiments. Mutagenicity: Based on available data the classification criteria are not met. Teratogenicity: Based on available data the classification criteria are not met. Reproductive toxicity: Based on available data the classification criteria are not met.
Specific target organ toxicity (single exposure)	Target Organs: Eyes Causes damage to organs.
Specific target organ toxicity (repeated exposure)	This information is not available.
Aspiration hazard	This information is not available.

12. ECOLOGICAL INFORMATION**12.1 Toxicity****Aquatic toxicity**

Sodium azide: LC50 *Lepomis macrochirus* (Bluegill sunfish): 0.7 mg/l; 96 h (ECOTOX Database)
EC50 *Daphnia pulex* (Water flea): 4.2 mg/l; 48 h (ECOTOX Database)
IC50 mixed culture of green algae: 272 mg/l(Lit.)
EC50 *Photobacterium phosphoreum*: 38.5 mg/l(Lit.)

Methanol: Toxicity to fish LC50 – *Lepomis macrochirus* – 15400 mg/l – 96 h

12.2 Persistence and degradability

Methanol: Biodégradability: 99% 30d

12.3 Bioaccumulative potential

Sodium azide: Partition coefficient: n-octanol/water:log Pow: 0.3
OECD Test Guideline 117
Bioaccumulation is not expected.

Methanol: Partition coefficient: n-octanol/water - log Pow: -0.77 (experimental)

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

Sodium azide : Forms toxic mixtures in water, dilution measures notwithstanding.
Herbicide
Nematocidal effect.
Discharge into the environment must be avoided.

Methanol: Discharge into the environment must be avoided

13. DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (91/689/EEC). Follow local regulations for radioactive waste.

Packaging/container: Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- Radioactive material should be disposed of following local regulations regarding radioactive waste.
- Patient samples, ¹²⁵I 1,25(OH)₂-Vitamin.D, Calibrators 1 to 5, Controls 1 and 2, Reconstitution Solution and Elution Solution are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

14. TRANSPORT INFORMATION

Radioactive material, N.O.S., UN 2910 - except package

Land transport AIEA/ADR/RID regulation (Class 7, fiche 1 - ADR)
Sea transport IMDG regulation
Air transport OACI/IATA regulation

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the mixture
no data available

15.2 Chemical Safety assessment
no data available

16. OTHER INFORMATION

16.1 Indication of changes
v1: SDS changes as required by current REACH regulation (as amended by 453/2010).
 Classification and labeling according to CLP added.

16.2 Abbreviations and acronyms
T+ Very toxic
N Dangerous for the environment
F Flammable
STOT SE Specific target organ toxicity - single exposure

16.3 Key literature references and sources for data
SDS sheets provided by suppliers of raw materials.

16.4 Classification and procedure used to derive the classification for mixtures according to regulation EC 1272/2008 – CLP

Classification of mixtures is based on the calculation method.

16.5 Relevant R-phrases and/or H-P statements

R11 Highly Flammable
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed
R28 Very toxic if swallowed
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R50 Very toxic to aquatic organisms
R53 May cause long term adverse effects in the aquatic environment



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- H225 Highly flammable liquid and vapour
H301+311+331 Toxic if swallowed, in contact with skin or if inhaled
H370 Causes damage to organs (Eyes)
H413 May cause long lasting harmful effects to aquatic life
- P273 Avoid release to the environment
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P233 Keep container tightly closed
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection
P302+352 IF ON SKIN: Wash with plenty of soap and water
P304+340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P308+310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician
P391 Collect spillage
P403+235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container to ...

16.7 Training advice

This product is designed for use by professionals.

16.8 Further information

NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

This MSDS assumes that radioprotection principles and applicable regulations are known by the user.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

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