

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- | | | |
|-----|----------------|---|
| 1.1 | Product name | DIASOURCE 25OH-VIT.D3-RIA-CT kit |
| | Catalog # | KIP1961 |
| | Kit components | Anti 25OH-Vitamin.D3 coated tubes
Calibrator 0
Calibrators 1 to 5
¹²⁵ I - 25OH-Vitamin.D3
Tracer buffer
Controls 1 and 2
Incubation buffer
Acetonitrile
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: products.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)****Acetonitrile**

Flammable liquid cat. 2

Acute toxicity cat. 4

Eye irritation cat. 2

2.1.2 Additional Information

Classification according to radioprotection regulations.

¹²⁵I - 25OH-Vitamin.D3

Contains radioactive material

2.2 Label elements:

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

Acetonitrile

H225-H302+312+332-H319

P210-P280-P240-P302+352-P305+351+338-P308+P310-P403+233

Danger

2.2.2 Labeling according to radioprotection regulations

¹²⁵I - 25OH-Vitamin.D3

2.2.3 Other labeling

Tube : each tube can only be used once**2.3 Other hazards:**

¹²⁵ I - 25OH-Vitamin.D3	Contains material from bovine origin Tracer: 160 kBq
Incubation buffer	Contains material from bovine origin
Controls	Contains material from human origin
Calibrator	Contains material from equine 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
Hazardous ingredients:

Component	Classification	concentration
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Incubation Buffer, Tracer Buffer 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		

Acetonitrile containing:
Acetonitrile

CAS-No.	75-05-8	Flammable liquid 2, H225; Acute toxicity 3,H302+312+332; Eye irritation 2, H319 F, Xn, Xi; R11-20/21/22-36	100%
EC-No.	200-835-2		
Index-No.	608-001-00-3		

4. FIRST AID MEASURES
4.1 Description of first aid measures
Acetonitrile

- After skin contact:*
- Flush skin with plenty of water for at least 15 minutes, while removing contaminated clothing and shoes.
 - Wash clothing before re-use.
 - Consult physician.
- After eye contact:*
- Flush immediately with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.
 - Consult physician.
- After ingestion:*
- Keep cyanide antidote kit on hand at all times if swallowed.
 - If unconscious, break an amyl nitrite pearl in a cloth and hold lightly under nose for 15 seconds; give oxygen.
 - Induce vomiting, when consciousness returns.
 - Consult immediately a physician
- After inhalation:*
- Break an amyl nitrite pearl in a cloth and hold lightly under nose for 15 seconds. Repeat 5 times at about 15 seconds intervals.
 - If he does not breathe, proceed to artificial respiration or provide oxygen.

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



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- 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.

5. FIRE FIGHTING MEASURES

Acetonitrile

Suitable extinguishing media:

Unsuitable extinguishing media:

Special exposure hazards:

Instructions:

Special protective equipment for firefighters:

- Dry chemical powder, alcohol foam or carbon dioxide
- No data available
- 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.
- Contact with oxidizers may cause fire.
- Due to small quantities: no special instructions apply
- Wear a self-contained breathing apparatus with full facepiece operated in positive pressure mode.
- Wear proper protective clothing to avoid all contact with the skin and eyes.
- Move containers from fire area if it can be done without risk

All Other Kit Components

Suitable extinguishing media:

Unsuitable extinguishing media:

Special exposure hazards:

Instructions:

Special protective equipment for firefighters:

- Powder, water, carbon dioxide, dry sand
- No data available
- No generation of hazardous or toxic gases in dangerous quantities
- Due to small quantities: no special instructions apply
- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Acetonitrile

Personal protection: see 7

Environmental precautions:

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

Clean-up:

- Cover with sand, or other non-combustible absorbent material.
- Place in covered containers using non-sparking tools and transport outdoors.
- Ventilate area and wash spill site after material pickup is complete
- Flush area with water
- Evacuate area
- Shut off all sources of ignition
- Do not allow spill to enter drains, sewer system, or natural water supplies.



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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

7. HANDLING AND STORAGE

Acetonitrile

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, direct sunlight 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



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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	No. Value	ppm
Acetonitrile CAS 75-05-8	Germany	DFG	34 mg/m ³
		AGS	20
	Denmark		40
	Finland		20
	France		40
	UK	EH40	40
	Norway		30
	Austria	GVK	40
	Sweden	AFS	60
	Belgium		20
	EU	REACH	68 mg/m ³

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

Acetonitrile

See 7.

All Other Kit Components

Eye protection: - Safety goggles (¹²⁵I - 25OH-Vitamin.D3)

- Face shield (Other components)

Hand protection: - Gloves

Suitable materials: - No data available



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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 : 6.4×10^{14} Bq.g⁻¹

Coated Tubes: Tubes

Controls 1 and 2, Standards 1 to 5, ¹²⁵I - 25OH-Vitamin.D3 : Lyophilized

Other components: Liquid

Acetonitrile :

Liquid

Boiling Point : 82°C

Flashpoint : 5°C

Specific gravity : 0.79

9.2 Other Information

No data available

10. STABILITY AND REACTIVITY

Acetonitrile

Keep container tightly closed. Keep out of sunlight. Isolate from incompatible materials.

All Other 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.

Acetonitrile:

Acute oral toxicity

LD50 mouse: 617 mg/kg
OECD Test Guideline 401

Absorption symptoms

Nausea, Vomiting

Acute inhalation toxicity

LC50 mouse: 6,022 mg/l; 4 h ; vapour

Acute dermal toxicity

OECD Test Guideline 403

LD50 rabbit: > 2.000 mg/kg

OECD Test Guideline 402 (Regulation (EC) No 1272/2008, Annex VI)

Skin irritation

rabbit

Result: No skin irritation

OECD Test Guideline 404

Eye irritation

rabbit

Result: Eye irritation

OECD Test Guideline 405

Causes serious eye irritation.

Sensitisation

Buehler Test guinea pig

Result: negative

Method: OECD Test Guideline 406

Germ cell mutagenicity

Genotoxicity in vivo

In vivo micronucleus test

mouse

Result: negative

Method: OECD Test Guideline 474

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

(External MSDS)

Mutagenicity (mammal cell test):

Mouse lymphoma test

Result: negative

Method: OECD Test Guideline 476

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

CMR effects

Carcinogenicity:

Based on available data the classification criteria are not met.

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

The substance or mixture is not classified as specific target organ toxicant, single exposure.

Specific target organ toxicity - repeated exposure

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

rat (male and female)
Inhalation vapour 91 d
NOAEL: 0,681 mg/l
(External MSDS)

Aspiration hazard

This information is not available.

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.

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.

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.)

Acetonitrile: Toxicity to fish

LC50 *Oryzias latipes* (Orange-red killifish): > 100 mg/l; 96 h

Toxicity to daphnia and other aquatic invertebrates

Daphnia magna (Water flea): > 1.000 mg/l; 48 h

Daphnia magna (Water flea): 960 mg/l; 21 d

Toxicity to algae

Pseudokirchneriella subcapitata (green algae): > 1.000 mg/l; 72 h

Pseudokirchneriella subcapitata (green algae): > 1.000 mg/l; 72 h

IC50 Scenedesmus quadricauda (Green algae): 7.300 mg/l; 8 d (IUCLID) (maximum permissible toxic concentration)

Toxicity to bacteria

EC50 Pseudomonas putida: 680 mg/l; 16 h (IUCLID) (maximum permissible toxic concentration)

12.2 Persistence and degradability

Acetonitrile: Biodegradability 70 %; 21 d (OECD Test Guideline 310)

Readily biodegradable.

12.3 Bioaccumulative potential

Sodium azide: Partition coefficient: n-octanol/water: log Pow: 0.3

OECD Test Guideline 117

Bioaccumulation is not expected.

Acetonitrile: Partition coefficient: n-octanol/water: log Pow: -0,34 (IUCLID)

Bioaccumulation: Bioconcentration factor (BCF): 0,3 :Lepomis macrochirus

Does not significantly accumulate in organisms.

12.4 Mobility in soil

Acetonitrile: Adsorption/Soil: log Koc: 1,21

Mobile in soils (Lit.)

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.

Acetonitrile: Hazard for drinking water supplies.

Further information on ecology

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 - 25OH-Vitamin.D3, Calibrators 0 to 5, Controls 1 and 2 and Incubation buffer 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

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

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
Xn Harmful
Xi Irritant

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
R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R28 Very toxic if swallowed



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R36 Irritating to eyes
R50 Very toxic to aquatic organisms
R53 May cause long term adverse effects in the aquatic environment

H225 Highly flammable liquid and vapour
H302 Harmful if swallowed
H312 Harmful in contact with skin
H319 Causes serious eye irritation
H332 Harmful if inhaled
H413 May cause long lasting harmful effects to aquatic life

P240 Ground/bond container and receiving equipment.
P273 Avoid release to the environment
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/protective clothing/eye protection/face protection
P302+352 IF ON SKIN: Wash with plenty of soap and water.
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+310 IF exposed or concerned : Immediately call a POISON CENTER or doctor/physician.
P391 Collect spillage
P403+233 Store in a well-ventilated place. Keep container tightly closed

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.

16.9 Notification:



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English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

MSDS established : 2021-02-25

Revision number : 7