



MATERIAL SAFETY DATA SHEET

(According to 91/155/EEC et seq.)

Product Name: DIASOURCE 25OH-VIT.D3-RIA-CT kit

Catalog #: KIP1961

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
¹²⁵I - 25OH-Vitamin.D3
Tracer buffer
Controls 1 and 2
Incubation buffer
Acetonitrile
Washing Solution
- 1.2 Company DIASource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
- 1.3 In emergencies Call your local emergency centre

2. COMPONENTS AND HAZARDOUS INGREDIENTS

¹²⁵ I - 25OH-Vitamin.D3	Contains material from bovine origin Tracer: 160 kBq	
Incubation buffer	0.05% Sodium azide (NaN ₃) Contains material from bovine origin	T+, N, R28-32-50/53
Tracer buffer	0.05% Sodium azide (NaN ₃)	T+, N, R28-32-50/53
Controls 1 and 2	Contains material from human origin	
Calibrator 0	Contains material from equine origin	
Calibrators 1 to 5	Contains material from equine origin	
Acetonitrile	Pure acetonitrile	Xn, F, R11-20/21/22-36

3. HAZARDS IDENTIFICATION

¹²⁵I - 25OH-Vitamin.D3

Animal proteins are potentially infectious
Contains radioactive material

Acetonitrile

Highly Flammable
Harmful by inhalation, in contact with skin and if swallowed
Irritating to the eyes

Control 1 and 2

Contains material of human origin. Although these 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.

Calibrators 1 to 5, Calibrator 0, Incubation buffer

Animal proteins are potentially infectious

4. FIRST AID MEASURES**¹²⁵I - 25OH-Vitamin.D3**

- After skin contact:*
- Wash immediately with soap and plenty of water for at least 10 minutes.
 - Consult a physician in case of inflammation.
- After eye contact:*
- In the case of a wound or cut rinse with plenty of water, then dress the wound.
 - 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
- After inhalation:*
- Transfer the person to an open place.
 - If he does not breathe, proceed to artificial respiration or provide oxygen.
 - Consult a physician.

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.

5. FIRE FIGHTING MEASURES**Acetonitrile**

- Suitable extinguishing media:*
- Dry chemical powder, alcohol foam or 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.



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Instructions:

Special protective equipment for firefighters:

- 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:

- Powder, water, carbon dioxide, dry sand
- No data available
- No generation of hazardous or toxic gases in dangerous quantities

Instructions:

Special protective equipment for firefighters:

- 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.

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



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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

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
- Skin protection:* - Protective clothing

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

9. PHYSICAL AND CHEMICAL PROPERTIES



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I¹²⁵

Half-life : 59.9 days

Specific activity : 6.4×10^{14} Bq.g⁻¹

Coated Tubes: Tubes

Bond Elut Silica Cartridges : Cartridges

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

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

I¹²⁵ labeled component(s)

Chronic and acute effects

General

- 0.25-2 Gy (single dose): chronic lymphocyte abnormalities, changes in blood counts, depressed immune defences, asthenia and nausea
- 2-7 Gy (single dose): haematopoietic syndrome, anaemia, haemorrhaging, depressed immune defences and possibility of death
- > 20 Gy: nervous syndrome, convulsions, coma and death.

Eyes:

- 2-5 Gy causes a cataract after some 5 years.
- 2 Gy received in fractionated doses over a few weeks may cause a cataract.
- > 16 Gy received in fractionated doses will always lead to cataract formation.

Skin:

- 5 Gy: vasodilatation, erythema, temporary loss of hair and body hair.
- 10 Gy: first-degree burn, dry epidermitis with cell death
- 20 Gy: second-degree burn, exudative epidermitis with cell death.
- > 25 Gy: deep necrosis with ulceration.

Gonads:

- 0.3 Gy (men), 3 Gy (women) : transient sterility



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- 5 Gy (men), 7 Gy (women) : irreversible sterility

Routes of exposure

Ingestion, inhalation, eyes and skin

Acetonitrile

Acute effects

Causes skin irritation

May be harmful if absorbed through the skin

Causes eye irritation

May be harmful if inhaled : headache, nausea, vomiting, dizziness, rapid ineffective breathing, low blood pressure, weakness, convulsions, cyanosis, unconsciousness, pulmonary edema, may be fatal.

Irritating to mucous membranes and upper respiratory tract

May be harmful if swallowed : cyanosis, unconsciousness, headache, nausea, vomiting, dizziness, weakness, rapid ineffective breathing, low blood pressure, gastrointestinal irritation, convulsions, may be fatal.

Chronic effects

Target organs : nerves, liver, heart, eyes, skin, blood, cardiovascular system, lungs.

Effects : central nervous system damage, blurred vision, liver damage, kidney damage, anemia, irritation of respiratory system.

Is not classifiable as to its carcinogenicity

Other components

Other components do not contain substances with a known chronic effect (e.g. carcinogenicity, mutagenicity, toxicity to reproduction).

Caution! Some components contain (a) substance(s) that are absorbed through the skin

12. ECOLOGICAL INFORMATION

Radioactivity

Dispose of following local regulations and guidelines.

Other information

- | | |
|---------------------------------------|--|
| - Effect on the ozone layer: | Not dangerous for the ozone layer (1999/45/EC) |
| - Greenhouse effect: | No data available |
| - Effect on waste water purification: | No data available |

13. WASTE 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, ^{125}I - 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

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

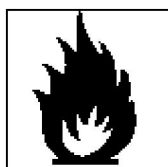
Land transport	AIEA/ADR/RID regulation (Class 7, fiche 1 - ADR)
Sea transport	IMDG regulation
Air transport	OACI/IATA regulation

15. REGULATORY INFORMATION

Classification according to directives 67/548/EEC, 1999/45/EC and radioprotection regulations.

 ^{125}I - 25OH-Vitamin.D3**Acetonitrile**

Harmful



Highly flammable

R11	: Highly flammable
R20/21/22	: Harmful by inhalation, in contact with skin and if swallowed
R36	: Irritating to eyes
S16	: Keep away from sources of ignition – no smoking
S36/37	: Wear suitable protective clothing and gloves



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16. OTHER INFORMATION

This product is designed for use by professionals.

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

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 DIA has not been reported.

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 a 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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