MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006)
Product name: DIASOURCE 25OH Vitamin D Total RIA
Catalog #: KIP1971

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE 25OH Vitamin D Total RIA
	Catalog #	KIP1971
	Kit components	Anti-25OH Vitamin D total Coated tubes ^{125}I labelled 25OH Vitamin D Calibrators 0 to 5 Controls 1 and 2 Tracer Buffer with casein and gentamycin Pre-treatment Solution with Proclin 300 (0.1 %) Pre-treatment Buffer Dilution Buffer with sodium azide (<0.1%) Washing Solution
1.2	Intended Use	In vitro diagnostic use
1.3	Company	DIAsource ImmunoAssays S.A. Rue de l'Industrie, 8 B-1400 Nivelles Belgium e-mail: tech.support@diasource.be
1.4	In emergencies	Call your local emergency centre

2. HAZARDS IDENTIFICATION

^{125}I labelled 25OH Vitamin D
Animal proteins are potentially infectious.
Contains radioactive material.

Controls 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 0 to 5
Animal proteins are potentially infectious.

Tracer buffer
Animal proteins are potentially infectious.

Pre-treatment solution
Irritating to skin, respiratory and gastrointestinal system. Moderately irritating to eyes.
May cause sensitization by inhalation.

Dilution buffer
Animal proteins are potentially infectious.

3. COMPONENTS AND HAZARDOUS INGREDIENTS

Classification

^{125}I labelled 25OH Vitamin D
Contains material from bovine origin
Tracer: 160 kBq

Controls 1 and 2
Contains material from human origin

Calibrators 0 to 5
Contains material from equine origin

Tracer buffer
Contains material from bovine origin

Pre-treatment solution S, I, R36-37-38-42-43

Dilution buffer
Contains material from bovine origin
0.05% sodium azide T+, N, R28-32-50/53

4. FIRST AID MEASURES

^{125}I labelled 25OH Vitamin D

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.

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

After inhalation:
- Transfer the person to an open place.
- If he does not breathe, proceed to artificial respiration or provide oxygen.
- Consult a physician.

Pre-treatment solution

After skin contact:
- Wash immediately with soap and plenty of water for at least 10 minutes.
- Consult a physician in case of persisting irritation.
- Remove and wash contaminated clothing before re-use.

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

After inhalation:
- Transfer the person to an open place.
- If he does not breathe, proceed to artificial respiration or provide oxygen.
- Consult a physician.

5. FIRE FIGHTING MEASURES

All 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

All 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 water
- Wash clothing according to radioprotection rules

7. HANDLING AND STORAGE

All 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

Specific purposes:

- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limits

Sodium Azide:

	mg/m^3	ppm
TLV-TWA	-	-
TLV-STEL	-	-
TLV-Ceiling	0.29 (NaN_3)	0.11 (HN_3)
OES-LTEL	-	-
OES-STEL	0.3 (NaN_3)	-
MAK	0.2	
TRK		
MAC-TGG 8h		
MAC-TGG 15min		
MAC-Ceiling	0.3	
VMA 8h	-	-
VMA 15min	0.3	0.1
GWBB 8h	-	-
GWBB 15min	-	-
Momentary value	0.29	0.11
EC	0.1	-
EC-STEL	0.3	-

8.2 Control of Exposure

8.2.1 Exposure to persons

All Kit Components

Respiratory Protection - Insufficient ventilation: wear respiratory protection
Hand Protection - Gloves
Eye Protection - Safety goggles (^{125}I labelled 25OH Vitamin D)
- Face shields
Skin Protection - Protective Clothing

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

8.2.2 Exposure to environment

Dilution buffer (containing Sodium Azide):
Aquatic Classification: not dangerous for the environment at the concentration present in the preparation (< 0.25%)
Ozone Classification: No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

I^{125}
Half-life: 59.9 days
Specific activity: 6.4 x 10^{14} $Bq.g^{-1}$
Coated Tubes: Tubes
Controls 1 and 2, Calibrators 0 to 5, Pre-treatment solution and ^{125}I labelled 25OH Vitamin D: Lyophilized, soluble in water
All other components: Liquid

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

I^{125} 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

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

Routes of exposure
Ingestion, inhalation, eyes and skin

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

12.1 Ecotoxicity

Aquatic toxicity

Sodium azide: - LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
- LC50 (96 h) : 0.7 mg/l (LEPOMIS MACROCHIRUS)
- LC50 (48 h) : 9 mg/l (GAMMARUS SP.)

Radioactivity
Dispose of following local regulations and guidelines.

12.2 Mobility
No information available.

12.3 Persistence and degradability
Not readily degradable

12.4 Bioaccumulation
The substance is considered as not bioaccumulative: Log Pow = NA
BCF = NA

12.5 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 labelled 25OH Vitamin D, Calibrators 0 to 5, Controls 1 and 2, Tracer buffer and

Dilution 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 labelled 25OH Vitamin D

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.

Risk phrases referred to in paragraph 3:
R28: Very toxic if swallowed
R32: Contact with acids liberates very toxic gas
R36: Irritating to eyes
R37: Irritating to respiratory system
R38: Irritating to skin
R42: May cause sensitisation by inhalation
R43: May cause sensitisation by skin contact
R50: Very toxic to aquatic organisms
R53: May cause long-term adverse effects in the aquatic environment

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.

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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