MATERIAL SAFETY DATA SHEET

(According to 91/155/EEC et seq.)
Product Name: DIASOURCE IGF 2-RIA-CT kit
Catalog #: KIPMR30

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE IGF 2-RIA-CT kit
	Catalog #	KIPMR30
	Kit components	Acidification Buffer Calibrators 0-7 Tracer: ^{125}I –IGF-II Dilution Buffer Assay Buffer Controls 1 and 2 1st Antibody Non-specific binding 2nd Antibody Precipitation Reagent
1.2	Intended use	In vitro diagnostic use
1.3	Company	DIAsource ImmunoAssays S.A. Rue de l'Industrie, 8 B-1400 Nivelles Belgium
1.4	In emergencies	Call your local emergency centre

2. COMPONENTS AND HAZARDOUS INGREDIENTS

		EINECS	Indexnr.
^{125}I –IGF-II			
Tracer: <110 kBq			
Controls 1 and 2			
Contains material from human origin		-	-
1st Antibody			
Contains material from bovine origin		-	-
2nd Antibody			
Contains material from bovine origin		-	-
Acidification Buffer			
phosphoric acid < 2,5%	C; R34	231-633-2	015-011-00-6
Dilution Buffer			
phosphoric acid < 2,5%	C; R34	231-633-2	015-011-00-6

3. HAZARDS IDENTIFICATION

^{125}I –IGF-II
Contains radioactive material

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.

1st Antibody, 2nd Antibody
Animal proteins are potentially infectious

4. FIRST AID MEASURES

^{125}I –IGF-II

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.

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 an excess of water
- Wash clothing and equipment after handling

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limits
No information available

8.2 Control of exposure

8.2.1 Exposure to persons

All Kit Components

Eye protection:	- Safety goggles (^{125}I – IGF II)
	- 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.

8.2.2 Exposure to environment

No information available

9. PHYSICAL AND CHEMICAL PROPERTIES

I^{125}
Half-life : 59.9 days
Specific activity : 6.4 x 10^{14} $Bq.g^{-1}$

Controls 1 and 2, Calibrators 0-7, ^{125}I –IGF-II, 1st Antibody, Non-specific binding, 2nd Antibody : Lyophilized
Acidification Buffer, Dilution Buffer, Assay Buffer, Precipitation Reagent: 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
No data available

Radioactivity
Dispose of following local regulations and guidelines.

12.2 Mobility
No information available

12.3 Persistence and degradability
No information available

12.4 Bioaccumulation
No information available

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, Controls 1 and 2, 1st Antibody and 2nd Antibody 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.

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 IGF-II

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 2&3:
R34: Causes burns.

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.

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