MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)
Product name: DIASOURCE IGFBP-3-IRMA kit
Catalog #: KIP1171

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE IGFBP-3-IRMA kit
	Catalog #	KIP1171
	Kit components	Anti IGFBP-3 Coated tubes ^{125}I-anti-IGFBP-3 (monoclonal Abs) Calibrators 1 to 5 Dilution Buffer Controls 1 or 2 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)

^{125}I-anti-IGFBP-3 and Dilution Buffer
Aquatic acute cat. 1 – Aquatic chronic cat. 4

2.1.2 Classification according to Directive 1999/45/EC

^{125}I-anti-IGFBP-3 and Dilution Buffer
Dangerous for the environment

2.1.3 Additional Information

Classification according to radioprotection regulations.

^{125}I-anti-IGFBP-3
Contains radioactive material

2.2 Label elements:

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

No label required

2.2.2 Labeling according to radioprotection regulations

^{125}I-anti-IGFBP-3

2.3 Other hazards:

^{125}I-anti-IGFBP-3	Contains material from bovine origin Tracer: 700 kBq
Calibrators 1 to 5	Contains material from bovine origin.
Controls 1 and 2	Contains material from human 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
^{125}I-anti-IGFBP-3 and Dilution Buffer containing:		
Sodium azide		
CAS-No. 26628-22-8 EC-No. 247-852-1 Index-No. 011-004-00-7	Aquatic Acute 1- Aquatic chronic 4, H413 T+, N; R28, R50-53	< 0.05%

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.

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.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

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 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

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

All Kit Components

Respiratory Protection	- Insufficient ventilation: wear respiratory protection
Hand Protection	- Gloves
Eye Protection	- Safety goggles (^{125}I-anti-IGFBP-3)
	- Face shields
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

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

Coated Tubes: Tubes
Controls 1 or 2, Calibrators 1 to 5: Lyophilized, soluble in water
Washing Solution, ^{125}I-anti-IGFBP-3, Dilution Buffer: 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

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

I^{125} 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.
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.)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

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

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.

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, ^{125}I-anti-IGFBP-3, Calibrators 0 to 6, Dilution Buffer and Controls 1 and 2 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

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

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

R28 Very toxic if swallowed
R50 Very toxic to aquatic organisms
R53 May cause long term adverse effects in the aquatic environment

H413 May cause long lasting harmful effects to aquatic life

P273 Avoid release to the environment
P391 Collect spillage
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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