



MATERIAL SAFETY DATA SHEET

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

Product Name: DIASOURCE TSH-IRMA kit

Catalog #: KIR1891 – KIR1894

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- | | | |
|-----|----------------|--|
| 1.1 | Product name | DIASOURCE TSH-IRMA kit |
| | Catalog # | KIR1891 – KIR1894 |
| | Kit components | Anti-TSH Coated tubes
Anti-TSH- ¹²⁵ I
Standards 0
Standards 1 to 7
Controls 1 and 2
Washing Solution |
| 1.2 | Company | DIAsource ImmunoAssays S.A.
Rue de l'Industrie, 8
B-1400 Nivelles
Belgium |
| 1.3 | In emergencies | Call your local emergency centre |

2. COMPONENTS AND HAZARDOUS INGREDIENTS

Anti-TSH-¹²⁵I	0.05 % Sodium azide (NaN ₃) Contains material from bovine origin Contains material from murine origin Tracer: 700 kBq	T+, N, R28-32-50/53
Standard 0	Contains material from bovine origin	
Standards 1 to 7	Contains material from equine origin	
Controls 1 and 2	Contains material from human origin	

3. HAZARDS IDENTIFICATION

Anti-TSH-¹²⁵I
Animal material is potentially infectious
Contains radioactive material

Standard 0, Standards 1 to 7
Animal material is potentially infectious

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.

4. FIRST AID MEASURES

Anti-TSH-¹²⁵I
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 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



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- Storage temperature: see component label

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

All Kit Components

- Eye protection:*
- Safety goggles (Anti-TSH-¹²⁵I)
 - 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

^I¹²⁵

Half-life : 59.9 days

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

Coated Tubes: Tubes

Controls 1 and 2, Standard 0, Standards 1 to 7: Lyophilized, soluble in water

Washing Solution, Anti-TSH-¹²⁵I: 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

^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.

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, Anti-TSH-¹²⁵I, Standard 0, Standards 1 to 7, 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.
- 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.

Anti-TSH-¹²⁵I



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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.

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 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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