

(According to 91/155/EEC et seq.) Product Name: DIASOURCE TESTO-RIA-CT kit Catalog #: KIR1709

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

| 1.1 | Product name | DIASOURCE TESTO-RIA-CT kit |
|-----|----------------|---|
| | Catalog # | KIR1709 |
| | Kit components | Anti TESTO Coated tubes Buffered ¹²⁵ I testosterone Standard 0 Standards 1 to 5 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

| Buffered ¹²⁵ I testosterone | 0.025 % Sodium azide (NaN ₃) Contains material from bovine origin Tracer: 180 kBq | T+, N, R28-32-50/53 |
|--|---|---------------------|
| Standard 0 | Contains material from human origin | |
| Standards 1 to 5 | Contains material from human origin | |
| Controls 1 and 2 | Contains material from human origin | |

3. HAZARDS IDENTIFICATION

Buffered¹²⁵**I** testosterone

Animal material is potentially infectious Contains radioactive material

Controls 1 and 2, Standard 0, Standards 1 to 5

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

Buffered ¹²⁵I testosterone

| 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 |
| | - Do not apply neutralizing agents |



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| After ingestion: | - 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

All Kit Components



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| Eye protection: | Safety goggles (Buffered ¹²⁵I testosterone) 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 : $6.4 \times 10^{14} \text{ Bq.g}^{-1}$

Coated Tubes: Tubes **Controls 1 and 2, Standard 0, Standards 1 to 5:** Lyophilized, soluble in water **Washing Solution, Buffered**¹²⁵**I testosterone:** 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

Radioactivity related adverse effects are only observed at exposure levels that are very much higher than those experienced with the reagents in this kit.

Azide containing component(s)

Toxicity and effects

| Acute toxicity: | LD50 oral rat | : 27 mg/kg |
|-------------------|-----------------------|------------|
| | LD50 dermal rabbit | : 20 mg/kg |
| Acute effects: | Harmful if swallowed | |
| Chronic toxicity: | Carcinogenicity (TLV) | : A4 |

Routes of exposure

Ingestion, inhalation, eyes and skin Caution! These components contain (a) substance(s) that are absorbed through the skin

Other components



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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

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.

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, Buffered ¹²⁵I testosterone, Standard 0, Standards 1 to 5, 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 transportAIEA/ADR/RID regulation (Class 7, fiche 1 - ADR)Sea transportIMDG regulationAir transportOACI/IATA regulation

15. REGULATORY INFORMATION

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



MATERIAL SAFETY DATA SHEET (According to 91/155/EEC et seq.)

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Buffered ¹²⁵I testosterone



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.

| MSDS established | : 2001-09-30 |
|------------------------|--------------|
| Revision number | :1 |