

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	FREE TESTOSTERONE-RIA-CT
	Catalog #	KIP19000
	Kit components	Anti-Testosterone Coated tubes Testosterone- ¹²⁵ I Calibrator 0 Calibrators 1 to 6 Controls 1 and 2 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
1.4	In emergencies	Call your local emergency centre

2. COMPONENTS AND HAZARDOUS INGREDIENTS

Testosterone-¹²⁵I	<0.1 % Sodium azide (NaN ₃) T+, N, R28-32-50/53 EINECS nr. 247-852-1 Contains material from rabbits Tracer: <185 kBq
Calibrator 0	<0.1 % Sodium azide (NaN ₃) T+, N, R28-32-50/53 EINECS nr. 247-852-1 Contains material from human origin
Calibrators 1-6	<0.1 % Sodium azide (NaN ₃) T+, N, R28-32-50/53 EINECS nr. 247-852-1 Contains material from human origin
Controls 1 and 2	<0.1 % Sodium azide (NaN ₃) T+, N, R28-32-50/53 EINECS nr. 247-852-1 Contains material from human origin
Wash Solution	<0.1 % Sodium azide (NaN ₃) T+, N, R28-32-50/53 EINECS nr. 247-852-1

3. HAZARDS IDENTIFICATION

According to 1999/45/EG, the preparations are **not** classified as dangerous.

¹²⁵I-Testosterone

Animal proteins are potentially infectious
Contains radioactive material

Calibrators 0 to 6

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.

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**Testosterone-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
- 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 Controle 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 (¹²⁵I-Testosterone)
- 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

All components (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**I¹²⁵**

Half-life : 59.9 days

Specific activity : 1500-2000 µCie/mgr.

Coated Tubes: Tubes**Calibrators 0 to 6:** ready to use**Controls 1 and 2:** ready to use**Washing Solution:** Liquid**Testosterone-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**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, ¹²⁵I-Testosterone, Calibrators 0 to 6 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.
- 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.

¹²⁵I-Testosterone





MATERIAL SAFETY DATA SHEET

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

Product Name: DIASOURCE Free Testosterone-RIA-CT

Catalog #: KIP19000

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:

R28: Very toxic if swallowed

R32: Contact with acids liberates very toxic gas

R50/53: Very toxic to aquatic organisms, 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 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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