MATERIAL SAFETY DATA SHEET

(According to 91/155/EEC et seq.)
Product Name: DIASOURCE DHT-RIA-CT
Catalog #: KIPI9900

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DHT-RIA-CT
	Catalog #	KIPI9900
	Kit components	^{125}I-DHT Calibrator (stock solution) Ab-DHT Ab 2nd $KMnO_4$ Buffer Controls 1 and 2
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

^{125}I-DHT	< 0.1 % Sodium azide (NaN_3) Contains material from rabbits Tracer: < 185 kBq	T+, N, R28-32-50/53	EINECS nr. 247-852-1
Calibrator	Ethanol	F, R11	EINECS nr. 200-578-6
Ab-DHT	< 0.1 % Sodium azide (NaN_3) Contains material from rabbits	T+, N, R28-32-50/53	EINECS nr. 247-852-1
Ab 2nd	< 0.1 % Sodium azide (NaN_3) Contains material from sheep	T+, N, R28-32-50/53	EINECS nr. 247-852-1
$KMnO_4$	2%	O, Xn, N;R8-22-50/53	EINECS nr. 231-760-3
Buffer	< 0.1% Sodium azide (NaN_3)	T+, N, R28-32-50/53	EINECS nr. 247-852-1
Controls 1 and 2	< 0.1 % Sodium azide (NaN_3) Contains material from equine origin	T+, N, R28-32-50/53	EINECS nr. 247-852-1

3. HAZARDS IDENTIFICATION

^{125}I-DHT
Animal proteins are potentially infectious
Contains radioactive material

Calibrator
Highly Flammable

Ab-DHT, Ab-2nd , Controls 1 and 2
Animal proteins are potentially infectious

KMnO4
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

4. 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.
- Remove contaminated clothing

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 or if any complaints

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:	- Prevent fire fighting water from entering surface water or groundwater
Special protective equipment for firefighters:	- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.
Calibrator (containing ethanol)	- Combustible. Vapours heavier than air Forms explosive mixtures with air at ambient temperatures. Beware of backfiring. Development of hazardous combustion gases or vapours possible in the event of fire.

6. ACCIDENTAL RELEASE MEASURES

All Kit Components

Personal protection: see 8

Environmental precautions:
- Prevent soil and water pollution
- Do not allow to enter sewerage system; risk of explosion.
- 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
- Keep away from sources of ignition. Take measures to prevent electrostatic charging.
- 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
- Required when vapours/aerosols are generated

Hand Protection - Gloves, nitrile rubber, layer thickness: 0.40 mm, breakthrough time: > 120 min

Eye Protection - Safety goggles required

- 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

$KMnO_4$:

Aquatic Classification: Harmful to aquatic organisms, may cause long-term adverse effects in th aquatic environment.
Ozone Classification: No data available

Other reagents:

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

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

DHT I^{125}, Calibrator, Ab-2nd , KMnO4, Buffer: Liquid
Ab-DHT, Controls 1 and 2: Lyophilized, soluble in water

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)

Calibrator (containing ethanol)
Conditions/Materials to avoid: Warming
Risk of ignition or formation of inflammable gases or vapors with: alkali metals, alkaline earth metals, alkali oxides, strong oxidizing agents, halogen-halogen compounds, CrO3, chromyl chlride, ethylene oxide, fluorine, perchlorates, potassium permanganate, sulfuric acid, perchloric acid, permanganic acid, phosphorous oxides, nitric acid, nitrogen dioxide, uranium hexafluoride, hydrogen peroxide

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.

***Calibrator** (containing ethanol)*
Acute toxicity:
LC50 (inhalation, rat): 95.6 mg/l /4h (RTECS)
LD50 (oral, rat): 6200 mg/kg (IUCLID)

Specific symptoms in animal studies:
Eye irritation test (rabbit): not irritation (OECD 405)
Skin irritation test (rabbit): No irritation (OECD 404)

Subacute to chronic toxicity:
Sensitization test (Magnusson and Kligman): negative (IUCLID)
Bacterial mutagenicity: Salmonella typhimurium: negative.

Further toxicological information:
After inhalation of vapours: slight mucosal irritation. Risk of absorption.
After skin contact: After long exposure to the chemical: dermatitis
After eye contact: slight irritation
After swallowing large amounts: nausea and vomiting
Systemic effects: euphoria
After absorption of large quantities: dizziness, inebriation, narcosis, respiratory paralysis.

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

All components

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

KMnO4

Ecotoxicity
Not available
Do not allow to enter wates, waste water or soil.

Biological effect:
Harmful effect on aquatic organisms. May cause long-term adverse effects in the aquatic environment.
Bactericidal effect.

Calibrator (containing ethanol)

Ecotoxicity
In high concentrations: harmful effect on aquatic organisms. When used properly, no impairments in the function of waste water treatment plants are to be expected.
Fish toxicity: L. idus LC50: 8140 mg/l/48h (IUCLID)
Daphnia toxicity: Daphnia magna EC50: 9268 – 14221 mg/l/48h (IUCLID)
Maximum permissible toxic concentration:
Algeal toxicity: Sc. quadricauda IC5: 5000 mg/l/7d (Lit); Bacterial toxicity: Ps. putida EC5: 6500 ml/l/16h (IUCLID); Protozoa: E. sulcatum EC5: 65 mg/l/72h (Lit)

Further ecological data:
BOD5: 0.93 – 1.67 g/g (Lit); COD: 1.99 g/g (IUCLID); TOD: 2.10 g/g (Lit); BOD 74% from TOD /5d (IUCLID); COD 90% from TOD (Lit).
No ecological problems are to be expected when the product is handled and used with due care and attention

Rapid abiotic degradation (air)
Readily biodegradable; 94% (OECD 301 E)

No bioaccumulation is to be expected (log Pow < 1)

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, DHT-I^{125}, Ab-DHT, Ab-2^{nd} , 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.

^{125}I-DHT

Calibrator:

F

R11, S7-16

R11: Highly flammable
S7: Keep container tightly closed
S16: Keep away from sources of ignition – no smoking.

$KMnO_4$

R52: Harmful to aquatic organisms
R53: May cause long term adverse effects in the aquatic environment
S61: Avoid release to the environment. Refer to special instructions / Safety data sheets.

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:
R8: Contact with combustible material may cause fire.
R11: Highly flammable
R22: Harmful if swallowed
R28: Very toxic if swallowed
R32: Contact with acids liberates very toxic gas
R50: Very toxic to aquatic organisms
R53: 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.

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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