

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE E2-RIA-CT kit
	Catalog #	KIP0629
	Kit components	Anti-E2 Coated tubes ¹²⁵ I-E2 Tracer buffer Standard 0 Standards 1 to 6 Controls 1 and 2 Washing Solution Diluent Specimen
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)*****¹²⁵I-E2**

Flammable liquid cat. 2

Tracer buffer and Standards

Aquatic acute cat. 1 – Aquatic chronic cat. 4

2.1.2 Classification according to Directive 1999/45/EC**¹²⁵I-E2**

Flammable liquid

Tracer buffer and Standards

Dangerous for the environment

2.1.3 Additional Information

Classification according to radioprotection regulations.

¹²⁵I-E2

Contains radioactive material

2.2 Label elements:

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

¹²⁵I-E2



H225
P210

Danger

2.2.2 Labeling according to radioprotection regulations

¹²⁵I-E2



2.2.3 Other labeling

Tube : each tube can only be used once



2.3 Other hazards:

¹²⁵I-E2

Controls 1 and 2

Standards 1 to 6

Standard 0

Tracer Buffer

Tracer: 142 kBq

Contains material from human origin

Contains material from human origin

Contains material from human origin

Contains material from bovine 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.



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2-RIA-CT kit

Catalog #: KIP0629

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Component	Classification	concentration
¹²⁵I-E2 containing:		
Ethanol		
CAS-No. 64-17-5	Flammable liquid cat. 2, H225	> 95%
EC-No. 200-578-6	F, R11	
Index-No. 603-002-00-5		

Tracer buffer and Standards containing:		
Sodium azide		
CAS-No. 26628-22-8	Aquatic Acute 1- Aquatic chronic 4, H413	< 0.5%
EC-No. 247-852-1		
Index-No. 011-004-00-7	T+, N; R28, R50-53	

4. FIRST AID MEASURES

4.1 Description of first aid measures

¹²⁵I-E2

- After ingestion:*
- Wash out mouth with water provided person is conscious.
 - Call a physician.
- After inhalation:*
- Remove to fresh air.
 - If not breathing give artificial respiration.
 - If breathing is difficult, give oxygen.
 - Consult a physician.
- After skin contact:*
- Immediately wash skin with soap and copious amounts of water.
 - 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:*
- Immediately flush eyes with copious amounts of water for at least 15 minutes.
 - Consult immediately a physician
 - Do not apply neutralizing agents

Standard 0, Standards 1 to 6

- Eye contact:*
- Rinse immediately with water for 15 minutes
 - Do not apply neutralizing agents
 - Consult a doctor/medical service if irritation persists
- Skin contact:*
- Rinse with plenty of water
 - Remove clothing before washing
 - Consult a doctor/medical service if irritation persists
- After inhalation:*
- Remove the victim into fresh air
 - Unconscious: maintain adequate airway and respiration
 - Consult a doctor/medical service if breathing problems develop
- After ingestion:*
- Never give water to an unconscious person
 - Give nothing (little) to drink



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2-RIA-CT kit

Catalog #: KIP0629

- Consult a doctor/medical service if you feel unwell

All Other 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.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES

¹²⁵I-E2

- Suitable extinguishing media:*
- Water spray, carbon dioxide, dry chemical powder or appropriate foam.
- Unsuitable extinguishing media:*
- No data available.
- Special exposure hazards:*
- Vapor may travel considerable distance to source of ignition and flash back.
 - Container explosion may occur under fire conditions.
 - Flammable liquid.
 - Emits toxic fumes under fire conditions.
- Instructions:*
- Prevent contact with skin and eyes.
 - Use water spray to cool fire-exposed containers.
- Special protective equipment for firefighters:*
- Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

All Kit Components except ¹²⁵I-E2

- Suitable extinguishing media:*
- All non combustible extinguishing media allowed.
- 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:*
- Due to small quantities: no special instructions apply.

6. ACCIDENTAL RELEASE MEASURES

All Kit Components except ¹²⁵I-E2

Personal protection: see 8

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2-RIA-CT kit

Catalog #: KIP0629

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

¹²⁵I-E2

Personal protection: see 8

Environmental precautions:

- Cover with dry-lime, sand or soda ash.
- Shut off all sources of ignition.
- Evacuate area.

Clean-up:

- The radioactive material should be wiped up immediately.
- Discharge of absorbed material according to local regulations
- Place in covered containers using non-sparking tools and transport outdoors.
- Ventilate area and wash spill site after material pickup is complete.
- Wash clothing and equipment 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

8.1 Control parameters

Components with workplace control parameters

Component	Country	Source	Type	Value
Ethanol CAS 64-17-5	Poland		NDS	1900 mg/m ³
	Poland		NDSch	-
	Poland		NDSP	-
	Denmark	OEL	TWA	1900 mg/m ³
	Germany	TRGS 900	OEL	1900 mg/m ³
				11000 ppm
	Norway		OEL	950 mg/m ³
			550 ppm	



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2-RIA-CT kit

Catalog #: KIP0629

	Sweden		LLV	1000 mg/m ³
				500 ppm
	Switzerland	OEL	OEL	960 mg/m ³
				500 ppm
	United Kingdom	OEL	OEL	1920 mg/m ³
				1000 ppm

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

- Eye protection:* - Safety goggles (¹²⁵I-E2)
- 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**9.1 Information on basic 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:** Lyophilized, soluble in water**Washing Solution, ¹²⁵I-E2, Tracer Buffer, Standard 0, Standards 1 to 6:** 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*Conditions/Materials to avoid:* Keep away from metals and acids (Azide containing components)**11. TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects****Ethanol:**

Acute oral toxicity LD50 rat: 6.200 mg/kg (IUCLID)

Symptoms: Nausea, Vomiting

Acute inhalation toxicity LC50 rat: 95,6 mg/l; 4 h (RTECS)

Absorption symptoms: slight mucosal irritations

Acute dermal toxicity This information is not available.

Skin irritation

rabbit

Result: No irritation

OECD Test Guideline 404

Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.

Eye irritation

This information is not available.

Sensitisation

Sensitisation test (Magnusson and Kligman):

Result: negative

(IUCLID)



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2-RIA-CT kit

Catalog #: KIP0629

Germ cell mutagenicity	Genotoxicity in vitro Ames test Salmonella typhimurium Result: negative (National Toxicology Program)
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.
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

Ethanol: Toxicity to fish LC50 Leuciscus idus (Golden orfe): 8.140 mg/l; 48 h (IUCLID)

Toxicity to daphnia and other aquatic invertebrates

EC5 E.sulcatum: 65 mg/l; 72 h (Lit.)

EC50 Daphnia magna (Water flea): 9.268 - 14.221 mg/l; 48 h (IUCLID)

Toxicity to algae

IC5 Scenedesmus quadricauda (Green algae): 5.000 mg/l; 7 d (Lit.)

Toxicity to bacteria

EC5 Pseudomonas putida: 6.500 mg/l; 16 h (IUCLID)

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

Ethanol: Biodegradability 94 %; OECD Test Guideline 301E. Readily biodegradable.
Biochemical Oxygen Demand (BOD): 930 - 1.670 mg/g (5 d) (Lit.)
Theoretical oxygen demand (ThOD): 2.100 mg/g (Lit.)
Ratio COD/ThBOD: 90 % (Lit.)

12.3 Bioaccumulative potential

Ethanol: Partition coefficient: n-octanol/water: log Pow: -0,31 (experimental)
(Lit.) Bioaccumulation is not expected.

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

Ethanol : No interference with wastewater treatment plants are to be expected when used properly.
Further information on ecology
Discharge into the environment must be avoided.

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)

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, Standard 0, Standards 1 to 5, Tracer Buffer, 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

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods.

If the shipment exceed this quantity, please refer to the information given below:

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
F flammable
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

R11	Highly flammable
R28	Very toxic if swallowed
R50	Very toxic to aquatic organisms
R53	May cause long term adverse effects in the aquatic environment



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2-RIA-CT kit

Catalog #: KIP0629

- H225 Highly flammable liquid and vapour.
H413 May cause long lasting harmful effects to aquatic life
- P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
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.

16.9 Notification:

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

MSDS established : 2019-10-30

Revision number : 5