

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name:	CT-U.S.-IRMA
Catalog #:	KIP0429
Kit Components:	Coated tubes ¹²⁵ I labeled-tracer Calibrators (0 to 5) Controls (1 and 2) Specimen Diluent Washing Solution

1.2 Intended Use

For In Vitro Diagnostic Use. See product literature for details.

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: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.11

Centre Anti-Poisons (BE) 070 245 245

Please refer to your local Anti-Poison Center!

2 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:

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional Information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161

Environmental Hazard

Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable
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Special Precautions for users: No special precautions for users are required.

3 OTHER INFORMATION

3.1 General Precautions:

- The products are for professional laboratory use only.
- Users should have a thorough understanding of the Instructions for Use prior to their use of this kit.
- Good Laboratory Practices (GLP) should be followed to ensure the safe use and disposal of the reagents.
- Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
- Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
- Wear disposable latex gloves when handling reagents

3.2 Other hazard

Tracer	Contains material from bovine origin
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This kit 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.

Calibrators	Contains material from human origin
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Controls	Contains material from human origin
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Specimen Diluent	Contains material from human origin
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3.3 Labeling of tube:

Each tube can only be used once



TRACER**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY****1.1 Product identifier**

Product Name: Tracer

Catalog #: Component of KIP0429

1.2 Intended Use

For In Vitro Diagnostic Use. See product literature for details.

1.3 Company

DIAsource ImmunoAssays S.A.

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B-1348 Louvain-la-Neuve

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2 HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture**

Product Description	In vitro diagnostic reagent Red; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Not classified as hazardous per EC 1272/2008 (CLP/GHS)
Classification according to EC Directives 1999/45/EC and 67/548/EEC	Not classified as dangerous per EC Directives (1999/45/EC and 67/548/EEC)
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label elements**2.2.1 According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

Not classified as hazardous per EC 1272/2008 (CLP/GHS).

2.2.2 According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)



2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Hazardous Ingredients:		Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 26628-22-8 EINECS# 247-852-1 Index # 011-004-00-7	< 0.05	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2,8
2 - Substance with Community workplace exposure limits 8 - Present at concentration below the cut-off limits.				

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

4 FIRST AID MEASURES

4.1 Description of first aid measures

- Inhalation** If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.
- Eye Contact** If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.
- Skin Contact** In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.
- Ingestion** If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

Flammable properties: Nonflammable aqueous solution.

5.1 Extinguishing media

In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards: No special Hazards determined.

Hazardous Combustion Products: No Combustible products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment: Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

No further relevant information available.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration.

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up

Spill and Leak Procedures: As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Radioactive material is subject to the regulations of each country.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific Use(s)

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	0.29 mg/m ³ Ceiling (as NaN ₃); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
Sodium Azide CAS# 26628-22-8	
DFG MAK	0.4 mg/m ³ Peak (inhalable fraction); 0.2 mg/m ³ TWA MAK (inhalable fraction)
Sodium Azide CAS# 26628-22-8	
Ireland	0.1 mg/m ³ TWA (as NaN ₃); 0.3 mg/m ³ STEL (as NaN ₃); Potential for cutaneous absorption
Sodium Azide CAS# 26628-22-8	
IOELVs	Possibility of significant uptake through the skin; 0.1 mg/m ³ TWA; 0.3 mg/m ³ STEL
Sodium Azide CAS# 26628-22-8	
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Red	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	6,0	Coefficien of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid

Avoid contact with incompatible materials.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Toxicity Data for Hazardous****Ingredients**

Sodium Azide

CAS# 26628-22-8

Primary Routes of Exposure

Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg;

Dermal LD50 Rabbit 20 mg/kg

Skin Corrosion/Irritation**Serious eye damage/eye irritation****Respiratory/skin sensitization****Carcinogenicity**

Common routes of entry include inhalation, ingestion and eye/skin contact.

Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

No data available.

No data available.

No data available.

This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.**Germ cell mutagenicity**

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

Aspiration hazard

No data available.

Other information

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

12 ECOLOGICAL INFORMATION**12.1 Ecotoxicity****Fresh Water Species**

Sodium Azide

CAS# 26628-22-8

96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50

Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales

promelas: 5.46 mg/L [flow-through]

Microtox

No information available

Water Flea

No information available

Fresh Water Algae

No information available

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other adverse effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product Waste Disposal:

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines.

See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06.

Dispose in accordance with national, state and local waste regulations.

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:

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional Information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable

EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazard					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special precautions for user: No special precautions for users are required.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulation/legislation specific for the substance or mixture

Us Federal and State Regulations

SARA 313

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration.

CERCLA RG's, 40 CFR 302.4

Sodium Azide is listed.

California Proposition 65

Iodine 125 has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, DIAsource ImmunoAssays advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Sodium Azide is listed.

Pennsylvania RTK

Sodium Azide is listed.

EU regulations

This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

REACH 1907/2006 EC - Annex XIV

No ingredients listed.

- list of substances subject to authorization

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)



Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

2910

Ingredients on Ingredient Disclosure

Sodium Azide

List

Ingredient with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 1 Reactivity with water: 0 Contact: 1	Code 0 = None 1 = Slight 2 = Caution 3 = Severe
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Hazard Class, hazard statements and risk phrase description from section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LC50 - Lethal Concentration, 50%

LD50 - Lethal Dose, 50%

For further information, please contact your local DIAsource ImmunoAssays representative.

Notification:

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

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

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