

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: E2 – RIA - CT
 Catalog #: KIP0629
 Kit Components: Coated tubes
¹²⁵I labeled-tracer
 Tracer Buffer
 Diluent Specimen
 Calibrators (0 to 6)
 Controls (1 and 2)
 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

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 Buffer** Contains material from bovine origin

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.

Diluent Specimen Contains material from human origin**Calibrators** Contains material from human origin**Controls** Contains material from human origin**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 KIP0629

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

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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 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description Colorless; Clear; Liquid; Pungent

Classification according to EC 1272/2008 Flammable liquids Category 2

(CLP/GHS) Eye irritation Category 2

Classification according to US-OSHA Not classified as hazardous per US-OSHA HCS

(HCS 29 CFR 1910.1200) and UN GHS 2012 and UN GHS

2.2 Label elements according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Danger symbol



Signal word Danger

Product Identifier Ethanol (1:1)

Danger H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

Supplemental Hazard Information -

Prevention statements P210 Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

P233 Keep container tightly closed.

P240 Ground and bond container and receiving equipment.

P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.

P242 Use non-sparking tools.


Response statements

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage statements

-

Disposal statements

-

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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

Hazardous Ingredients:		Hazard Classification of Pure Ingredients	
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS
Ethanol CAS # 64-17-5 EINECS# 200-578-6 Index # 603-002-00-5	>95	Flam. Liq. 2 Eye Irrit. 2 H225, H3190	Flam. Liq. 2 Eye Irrit. 2 H225, H3190

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, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

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

Carbon oxides.

Combustible.

Pay attention to flashback.

Vapors are heavier than air and may spread along floors.

Development of hazardous combustion gases or vapours possible in the event of fire.

Forms explosive mixtures with air at ambient temperatures.

5.3 Advice for fire fighters

In the event of fire, wear self-contained breathing apparatus.

5.4 Additional information

Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental Precautions

Do not let product enter drains. Risk of explosion.

6.3 Methods and material for containment and cleaning-up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material.

Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Refer sections 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on protection against fire and explosion

Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

For precautions see section 2.2.

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.

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
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	Vapor Density	1.6
Color	Colorless	Odor threshold	Not applicable
Transparency	Clear	Specific Gravity (water = 1.0)	1.00 @20°C
Odor	Pungent	Solubility:	
pH	7.0	Water	Miscible
Freezing Point	-144.0°C @1013 hPa	Organic	Not applicable
Boiling Point	78.3°C @1013hPa	Coefficien of Water/Oil Distribution	Not determined
Flash Point	13°C	Autoignition Temp.	455.0°C @1013 hPa
Evaporate Rate	Not determined	Decomposition Temperature	Not determined
Flammability (Solid, Gas)	Not applicable	Percent Volatiles	Not determines
Flammable Limits:		Vapor Pressure	0.57hPa @19.6°C
Upper explosion limit	13.5%(V)	Viscosity	Not determined
Lower explosion limit	2.5%(V)	Explosive Properties	Not applicable

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

Vapors may form explosive mixture with air.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

Warming.

10.5 Incompatible materials

Rubber, various plastics.

10.6 Hazardous Decomposition Products

In the event of fire: see section 5.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Primary Routes of Exposure	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.
Acute Toxicity	LD50 Oral - Rat – 10,470 mg/kg (OECD Test Guideline 4021) LD50 Dermal - Rat - male and female – 4h – 124.7 mg/l (OECD Test Guideline 403)
Skin Corrosion/Irritation	Skin - Rabbit Result: No skin irritation - 24 h (OECD Test Guideline 404)
Serious eye damage/eye irritation	Eyes – Rabbit Result: Causes serious eye irritation (OECD Test Guideline 405)
Respiratory/skin sensitization	Maximization Test - Guinea pig Result: negative (OECD Test Guideline 406)
Carcinogenicity	Not classified based on available data.
Germ cell mutagenicity	Test Type: Ames test Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 476 Result: negative Test Type: dominant lethal test

Reproductive Toxicity**Specific target organ toxicity - single exposure****Specific target organ toxicity - repeated exposure****Aspiration hazard****Other information**

Species: Mouse

Application Route: Oral

Method: OECD Test Guideline 478

Result: Positive results were obtained in some in vivo tests

Not classified based on available data.

Not classified based on available data.

Not classified based on available data.

Not classified based on available data.

Repeated dose toxicity - Rat - male - Oral - NOAEL (No observed adverse effect level) - 1,730 mg/kg - LOAEL (Lowest observed adverse effect level) - 3,200 mg/kg

irritant effects, respiratory paralysis, Dizziness, narcosis, inebriation, euphoria, Nausea, Vomiting

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12 ECOLOGICAL INFORMATION**12.1 Ecotoxicity****Toxicity to fish**

Flow-through test LC50 - Pimephales promelas (fathead minnow) - 15,300 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates

static test LC50 - Ceriodaphnia dubia (water flea) - 5,012 mg/l - 48 h

Toxicity to algae

Remarks: (ECHA)

Static test ErC50 - Chlorella vulgaris (Fresh water algae) - 275 mg/l - 72 h

Toxicity to bacteria

(OECD Test Guideline 201)

Static test IC50 - activated sludge - > 1,000 mg/l - 3 h

(OECD Test Guideline 209)

12.2 Persistence and degradability**Biodegradability**

Aerobic - Exposure time 15 d

Result: ca.95 % - Readily biodegradable.

(OECD Test Guideline 301E)

Biochemical Oxygen Demand (BOD)

930 - 1,670 mg/g

Remarks: (Lit.)

Theoretical oxygen demand

2,100 mg/g

Remarks: (Lit.)

12.3 Bioaccumulation

Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No interference with wastewater treatment plants are to be expected when used properly.

Discharge into the environment must be avoided.

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.

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	PIN - 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

No ingredients listed

CERCLA (The Comprehensive Environmental Response, Compensation and Liability Act) 40 CFR 302.4

No ingredients listed

California Proposition 65
WARNING: This product can expose you to chemical which is known to the State of California to cause cancer and/or harm. For more information, go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

Iodine 125 (CAS # 14158-31-7)

Chemical which is known to the State of California to cause development toxicity

No ingredients listed

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed

Massachusetts MSL

No ingredients listed

New Jersey Dept. of Health RTK List

No ingredients listed

Pennsylvania RTK

No ingredients listed

EU regulations

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

Water Hazard Class (Germany)

WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV

No ingredients listed.

- list of substances subject to authorization

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out...

Some hazardous ingredients listed in Section 15 are below the cutoff of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 2 Health: 2 Reactivity with water: 0 Contact: 2	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
<p>Hazard Class, hazard statements and risk phrase description from section 3 Flam. Liq. 2 – Flammable liquids, Category 2 Eye Irrit. 2 – Eye irritation, Category 2 H225 - Highly flammable liquid and vapor. H319 - Causes serious eye irritation.</p> <p>Abbreviations and Acronyms ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail 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 DGR - International Air Transport Association Dangerous Goods Regulation 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 LD50 - Lethal Dose, 50%</p>		

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

WHILE DIASOURCE IMMUNOASSAYS S.A. BELIEVES THE INFORMATION CONTAINED HERE IN IS VALID AND ACCURATE, DIASOURCE IMMUNOASSAYS MAKES NO WARRANTY OR REPRESENTATION AS TO ITS VALIDITY , ACCURACY , OR CURRENCY . DIASOURCE IMMUNOASSAYS SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR USE OF EITHER THIS INFORMATION OR MATERIALS TO WHICH IT APPLIES. DISPOSAL OF HAZARDOUS MATERIALS MAY BE SUBJECT TO LOCAL LAWS OR REGULATIONS.

TRACER BUFFER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tracer buffer
Catalog #: Component of KIP0629

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)10/84.99.23
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Mixture Yellowish; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Not classified as hazardous per EC 1272/2008 (CLP/GHS)
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).

2.3 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.

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	< 0.1	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 combustion 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 material of human origin and should be handled as though capable of transmitting infectious diseases. 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.

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

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.

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 end uses

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 No special engineering controls are required. Use with good general ventilation.

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.

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	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.0	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

Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg;
Dermal LD50 Rabbit 20 mg/kg

Primary Routes of Exposure

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.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens 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 human 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 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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	No ingredients listed.
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

Canada

This product does not meet WHMIS criteria for hazardous materials.

PIN Not applicable
Ingredients on Ingredient Disclosure List Sodium Azide
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	<u>Code</u> 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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DILUENT SPECIMEN

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Diluent Specimen
Catalog #: Component of KIP0629

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)10/84.99.23
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Mixture Yellowish; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Not classified as hazardous per EC 1272/2008 (CLP/GHS)
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).

2.3 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.

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	< 0.1	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 combustion 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 material of human origin and should be handled as though capable of transmitting infectious diseases. 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.

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

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.

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 end uses

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 No special engineering controls are required. Use with good general ventilation.

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.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.02 @20°C
Color	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	Not determined	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

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.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens 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 human 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

static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201

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 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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	No ingredients listed.
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

Canada

This product does not meet WHMIS criteria for hazardous materials.

PIN Not applicable
Ingredients on Ingredient Disclosure List Sodium Azide
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	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
---	--	--

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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CALIBRATORS

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Calibrators
Catalog #: Component of KIP0629

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)10/84.99.23
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Mixture Yellowish; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Not classified as hazardous per EC 1272/2008 (CLP/GHS)
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).

2.3 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.

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	< 0.5	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 combustion 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 material of human origin and should be handled as though capable of transmitting infectious diseases. 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.

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

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.

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 end uses

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 No special engineering controls are required. Use with good general ventilation.

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.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.02 @20°C
Color	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.4	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

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.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

No ingredients in this product are listed as carcinogens 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 human 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

static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201

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 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

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	No ingredients listed.
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

Canada

This product does not meet WHMIS criteria for hazardous materials.

PIN Not applicable
Ingredients on Ingredient Disclosure List Sodium Azide
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	<u>Code</u> 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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MSDS established : 2022-07-06

Revision number : 6