

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: SM-C - RIA - CT
 Catalog #: KIP1589
 Kit Components: Coated tubes
 Tracer
 Reconstitution Solution
 Pre-treatment Solution
 Neutralization Solution
 Calibrators (0 to 5)
 Controls (1, 2 and 3)
 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 Polluant	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	Contains material from bovine origin
Neutralization Solution	Contains material from bovine origin
Calibrators	Contains material from chicken 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.

Controls	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 KIP1589

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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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

In vitro diagnostic reagent
Colorless; 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.

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	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.0	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

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 Classification Code	None	None	None	None	None
Packing Group	Not applicable	Not applicable	Not applicable	None	Not applicable
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 California Proposition 65

Sodium Azide is listed.

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



Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 2910
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	<u>Code</u>
	Health: 1	0 = None
	Reactivity with water: 0	1 = Slight
	Contact: 1	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

WHILE DIASOURCE IMMUNOASSAYS S.A. BELIEVES THE INFORMATION CONTAINED HEREIN 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.

RECONSTITUTION SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Reconstitution Solution

Catalog #: Component of KIP1589

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 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS) Flammable liquids Category 3

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

Danger symbol



Signal word Warning

Product Identifier Ethanol

Danger H225 Highly flammable liquid and vapor.

Supplemental Hazard Information -

Prevention statements P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Response statements -

Storage statements -

Disposal statements
2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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	<15	Flam. Liq. 2 H225	Flam. Liq. 2 H225

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

General advice Show this material safety data sheet to the doctor in attendance.

Inhalation If product is inhaled, move exposed individual to fresh air.

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	Not determined
Color	Colorless	Odor threshold	Not determined
Transparency	Clear	Specific Gravity (water = 1.0)	1.0
Odor	Odorless	Solubility:	
pH	Not determined	Water	Miscible
Freezing Point	Not determined	Organic	Not applicable
Boiling Point	Not determined	Coefficien of Water/Oil Distribution	Not determined
Flash Point	Not determined	Autoignition Temp.	Not determined
Evaporate Rate	Not determined	Decomposition Temperature	Not determined
Flammability (Solid, Gas)	Not determined	Percent Volatiles	Not determines
Flammable Limits:		Vapor Pressure	Not determined
Upper explosion limit	Not determined	Viscosity	Not determined
Lower explosion limit	Not determined	Explosive Properties	Not determined

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

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	Not classified based on available data.
Skin Corrosion/Irritation	Not classified based on available data.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	Not classified based on available data.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity - single exposure	Not classified based on available data.
Specific target organ toxicity - repeated exposure	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other information	-

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Toxicity to fish	Not classified based on available data.
Toxicity to daphnia and other aquatic invertebrates	Not classified based on available data.
Toxicity to algae	Not classified based on available data.
Toxicity to bacteria	Not classified based on available data.

12.2 Persistence and degradability

Biodegradability	Not classified based on available data.
Biochemical Oxygen Demand (BOD)	Not classified based on available data.
Theoretical oxygen demand	Not classified based on available data.

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

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 and 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

No additional information.

14 TRANSPORT INFORMATION

	ADR	ADN/ADNR	IMDG	IATA
14.1. UN number	Not applicable			
14.2. UN proper shipping name	Not applicable			
14.3. Transport hazard class(es)	Not applicable		Not applicable	Not applicable
14.4. Packing group	Not applicable		Not applicable	Not applicable
14.5. Environmental hazards	Not available	Not available	Not available	Not available
Hazard label	Not applicable			
Classification code	Not applicable			
14.6. Special precautions for user	Not available			
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not available			
Other information	Not available	Not available	Not available	Not available

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 1 Health: 0 Reactivity with water: 0 Contact: 0	<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

Flam. Liq. 2 – Flammable liquids, Category 2

H225 - Highly flammable liquid and vapor.

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%

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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PRE-TREATMENT SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Pre-treatment Solution

Catalog #: Component of KIP1589

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 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 Flammable liquids Category 3

(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 > 85 %

HCl < 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.

Response statements

P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
 P242 Use non-sparking tools.
 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.

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	> 85	Flam. Liq. 2; Eye Irrit. 2; H225, H319	Flam. Liq. 2; Eye Irrit. 2; H225, H319

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
General advice Show this material safety data sheet to the doctor in attendance.

Inhalation If product is inhaled, move exposed individual to fresh air.

Eye Contact After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

Skin Contact In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

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	Not determined
Color	Colorless	Odor threshold	Not determined
Transparency	Clear	Specific Gravity (water = 1.0)	Not determined
Odor	Odorless	Solubility:	
pH	Not determined	Water	Miscible
Freezing Point	Not determined	Organic	Not applicable
Boiling Point	Not determined	Coefficien of Water/Oil Distribution	Not determined
Flash Point	Not determined	Autoignition Temp.	Not determined
Evaporate Rate	Not determined	Decomposition Temperature	Not determined
Flammability (Solid, Gas)	Not determined	Percent Volatiles	Not determines
Flammable Limits:		Vapor Pressure	Not determined
Upper explosion limit	Not determined	Viscosity	Not determined
Lower explosion limit	Not determined	Explosive Properties	Not determined

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

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	Not classified based on available data.
Skin Corrosion/Irritation	Not classified based on available data.
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	Not classified based on available data.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity - single exposure	Not classified based on available data.
Specific target organ toxicity - repeated exposure	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other information	-

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Toxicity to fish	Not classified based on available data.
Toxicity to daphnia and other aquatic invertebrates	Not classified based on available data.
Toxicity to algae	Not classified based on available data.
Toxicity to bacteria	Not classified based on available data.

12.2 Persistence and degradability

Biodegradability	Not classified based on available data.
Biochemical Oxygen Demand (BOD)	Not classified based on available data.
Theoretical oxygen demand	Not classified based on available data.

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

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 and 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

No additional information.

14 TRANSPORT INFORMATION

	ADR	ADN/ADNR	IMDG	IATA
14.1. UN number	Not applicable			
14.2. UN proper shipping name	Not applicable			
14.3. Transport hazard class(es)	Not applicable		Not applicable	Not applicable
14.4. Packing group	Not applicable		Not applicable	Not applicable
14.5. Environmental hazards	Not available	Not available	Not available	Not available
Hazard label	Not applicable			
Classification code	Not applicable			
14.6. Special precautions for user	Not available			
14.7. Transport in bulk according to Annex II of	Not available			

MARPOL73/78 and the IBC Code				
Other information	Not available	Not available	Not available	Not available

15 REGULATORY INFORMATION

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16 OTHER INFORMATION

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

Flam. Liq. 2 – Flammable liquids, Category 2

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

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%

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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NEUTRALIZATION SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Neutralization Solution

Catalog #: Component of KIP1589

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

Colorless; 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

Printing date 9/12/22

Compiled by:
DIAsource ImmunoAssays S.A
2 rue du Bosquet
1348 - Louvain-la-Neuve Belgium

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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 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	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	8.7	Coefficient 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.

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Reproductive Toxicity

Specific target organ toxicity - single exposure

Specific target organ toxicity - repeated exposure

Aspiration hazard

Other information

No data available.

No data available.

No data available.

No data available.

No data available.

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

Microtox

Water Flea

Fresh Water Algae

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]

No information available

No information available

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	<u>Code</u>
	Health: 1	0 = None
	Reactivity with water: 0	1 = Slight
	Contact: 1	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.
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CALIBRATORS

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Calibrators
Catalog #: Component of KIP1589

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 Colorless; 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
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Printing date 9/12/22

Compiled by:
DIAsource ImmunoAssays S.A
2 rue du Bosquet
1348 - Louvain-la-Neuve Belgium

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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 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	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.6	Coefficient 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.

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity

Reproductive Toxicity

Specific target organ toxicity - single exposure

Specific target organ toxicity - repeated exposure

Aspiration hazard

Other information

No data available.

No data available.

No data available.

No data available.

No data available.

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

Microtox

Water Flea

Fresh Water Algae

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]

No information available

No information available

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.

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REACH 1907/2006 EC - Annex XIV No ingredients listed.
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