

KIT

INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 **Product identifier**

1

Product Name:	PIIIP IRMA
Catalog #:	OCFK07-PIIIP
Kit Components:	Coated tubes ¹²⁵ I labeled-tracer Incubation Buffer 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**

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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!

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 Mater	ial, excepted package	-limited quantity of n	naterial	
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				
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

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Not applicable

Environmental Hazard

Hazard

Marine Polluant Not applicable

Not applicable

Not applicable

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

No

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 Calibrators

Contains material from bovine origin 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.

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 <u>Product identifier</u>

Product Name: Tracer

Catalog #:

Component of OCFK07-PIIIP

1.2 Intended Use

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

1.3 <u>Company</u>

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 <u>Emergency telephone</u>

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 <u>Classification of the substance or mixture</u>

Product Description

Classification according to EC 1272/2008 (CLP/GHS) Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS In vitro diagnostic reagent Red; Clear; Liquid; Odorless Not classified as hazardous per EC 1272/2008 (CLP/GHS) Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 <u>Label elements</u>

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

4

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS		
Sodium Azide	< 0.1	Acute Tox. Oral 2	Acute Tox. Oral 2	2,8	
CAS # 26628-22-8		Aquatic Acute 1	Aquatic Acute 1		
EINECS# 247-852-1		Aquatic Longterm 1	Aquatic Longterm 1		
Index # 011-004-00-7		H300; H400; H410	H300; H400; H410		
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

FIRST AID MEASURES

4.1 <u>Description of first aid measures</u>

Inhalation	If product is inhaled, move exposed individual to fresh air. If individual is not
Eye Contact	breathing, begin artificial respiration immediately and obtain medical attention. 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	
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 <u>Extinguishing media</u>

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 <u>Environmental Precautions</u>

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 <u>Reference to other sections</u>

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 <u>Precautions for safe handling</u>

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 <u>Specific Use(s)</u>

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 <u>Control parameters</u>

Exposure Limi US OSHA	its	None established	
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ACGIH Sodium Azide CAS# 26628-22-8	0.29 mg/m ³ Ceiling (as NaN ₃); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
DFG MAK Sodium Azide CAS# 26628-22-8	0.4 mg/m ³ Peak (inhalable fraction); 0.2 mg/m ³ TWA MAK (inhalable fraction)
Ireland Sodium Azide CAS# 26628-22-8	0.1 mg/m ³ TWA (as NaN ₃); 0.3 mg/m ³ STEL (as NaN ₃); Potential for cutaneous absorption
IOELVs Sodium Azide CAS# 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m ³ TWA; 0.3 mg/m ³ STEL
NIOSH Japan	None established None established
8.2 <u>Exposure controls</u>	
Engineering Controls Eye Protection	Place vial behind a metal shield, away from the user. Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or
Skin Protection	appropriate government standards. 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 Color	Liquid Red	Specific Gravity (water = 1.0) Solubility:	1.00 @20°C
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
рН	7,4	Coefficien of Water/Oil	Not determined
		Distribution	
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,	Not applicable	Viscosity	Not determined
Gas)			
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 <u>Other information</u>

No further relevant information available.



10 STABILITY AND REACTIVITY

10.1 <u>Reactivity</u>

No further relevant information available.

10.2 <u>Chemical Stability</u>

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 <u>Incompatible materials</u>

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 -	No data available.
repeated exposure	NY 1. 111
Aspiration hazard Other information	No data available.
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.
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	ue du Bosquet
134	48 - Louvain-la-Neuve Belgium



12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Fresh Water Species	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50
Sodium Azide	Lepomis macrochirus:0.7 mg/L; 96 h LC50 Pimephales
CAS# 26628-22-8	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 <u>Results of PBT and vPvB assessment</u>

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 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

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	ΙΑΤΑ	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Mate	rial, excepted package	e-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				
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 procesuti	ions for user. N	o special precauti	one for users are i	required	

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 <u>Safety, health and environmental regulation/legislation specific for the substance or mixture</u>

Us Federal and State Regulations

SARA 313 CERCLA RG's, California Prope		Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration. 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 N New Jersey Dep Pennsylvania R7	t. of Health RTK List	Sodium Azide is listed. Sodium Azide is listed. Sodium Azide is listed.	
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EU regulations

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

No ingredients listed.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization



<u>Canada</u>

This product is exempt from WHMIS label and SDS requirements.

PIN2910Ingredients on Ingredient DisclosureSodium AzideListProduct is exempttoxicological propertiesProduct is exempt

15.2 <u>Chemical Safety Assessment</u>

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	$\frac{\text{Code}}{0 = \text{None}}$ $1 = \text{Slight}$ $2 = \text{Caution}$
	Contact: 1	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



MATERIEL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

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

INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 <u>Product identifier</u>

Product Name: Calibrators

Catalog #: Component of OCFK07-PIIIP

1.2 Intended Use

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

1.3 <u>Company</u>

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 <u>Emergency telephone</u>

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 <u>Classification of the substance or mixture</u>

Product Description

Mixture

Classification according to EC 1272/2008 (CLP/GHS) Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS Yellowish; Clear; Lyophilised; Odorless Not classified as hazardous per EC 1272/2008 (CLP/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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MATERIEL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide	< 0.05	Acute Tox. Oral 2	Acute Tox. Oral 2	2,8
CAS # 26628-22-8		Aquatic Acute 1	Aquatic Acute 1	
EINECS# 247-852-1		Aquatic Longterm 1	Aquatic Longterm 1	
Index # 011-004-00-7		H300; H400; H410	H300; H400; H410	
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 <u>Description of first aid measures</u>

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
Ingestion	medical attention. 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 <u>Advice for fire fighters</u>

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 <u>Personal precaution, protective equipment and emergency procedures</u>

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 <u>Environmental Precautions</u>

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 <u>Reference to other sections</u>

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 <u>Precautions for safe handling</u>

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 <u>Control parameters</u>

Exposure Limits

US OSHA ACGIH Sodium Azide CAS# 26628-22-8 DFG MAK Sodium Azide CAS# 26628-22-8 Ireland Sodium Azide CAS# 26628-22-8 IOELVs Sodium Azide CAS# 26628-22-8 NIOSH Japan	 None established 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor) 0.4 mg/m³ Peak (inhalable fraction); 0.2 mg/m³ TWA MAK (inhalable fraction) 0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential for cutaneous absorption Possibility of significant uptake through the skin; 0.1 mg/m³ TWA; 0.3 mg/m³ STEL None established None established
Japan	None established
Printing date 2/12/22	Compiled by: Page 14/35 DIAsource ImmunoAssays S.A

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8.2 <u>Exposure controls</u>	
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 Color	lyophilised Yellowish	Specific Gravity (water = 1.0) Solubility:	1.00 @20°C
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
рН	7.4	Coefficien of Water/Oil	Not determined
		Distribution	
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,	Not applicable	Viscosity	Not determined
Gas)			
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 <u>Reactivity</u>

No further relevant information available.

10.2 <u>Chemical Stability</u>

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 <u>Hazardous Decomposition Products</u>

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
CAS# 26628-22-8 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 -	No data available.
repeated exposure	
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 <u>Ecotoxicity</u>

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 <u>Results of PBT and vPvB assessment</u>

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 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

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 <u>Safety, health and environmental regulation/legislation specific for the substance or mixture</u>

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.	
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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

<u>Canada</u>

This product does not meet WHMIS criteria for hazardous materials.

Not applicable
Sodium Azide
Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

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

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 H300 - Fatal if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany' s maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard





(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

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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CONTROLS

INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 <u>Product identifier</u>

Product Name: Controls

Catalog #: Component of OCFK07-PIIIP

1.2 Intended Use

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

1.3 <u>Company</u>

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 <u>Emergency telephone</u>

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 <u>Classification of the substance or mixture</u>

Product Description

Mixture

Classification according to EC 1272/2008 (CLP/GHS) Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS Yellowish; Clear; Lyophilised; Odorless Not classified as hazardous per EC 1272/2008 (CLP/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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MATERIEL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide	< 0.1	Acute Tox. Oral 2	Acute Tox. Oral 2	2,8
CAS # 26628-22-8		Aquatic Acute 1	Aquatic Acute 1	
EINECS# 247-852-1		Aquatic Longterm 1	Aquatic Longterm 1	
Index # 011-004-00-7		H300; H400; H410	H300; H400; H410	
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 <u>Description of first aid measures</u>

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
Ingestion	medical attention. 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 <u>Advice for fire fighters</u>

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 <u>Personal precaution, protective equipment and emergency procedures</u>

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 <u>Environmental Precautions</u>

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 <u>Reference to other sections</u>

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 <u>Precautions for safe handling</u>

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 <u>Control parameters</u>

Exposure Limits

US OSHA ACGIH Sodium Azide CAS# 26628-22-8		None established 0.29 mg/m ³ Ceiling (as NaN ₃); 0.11 ppm Ceiling (as Hyd (vapor)	razoic acid)
DFG MAK Sodium Azide CAS# 26628-22-8		0.4 mg/m ³ Peak (inhalable fraction); 0.2 mg/m ³ TWA MA (inhalable fraction)	AK
Ireland		0.1 mg/m ³ TWA (as NaN ₃); 0.3 mg/m ³ STEL (as NaN ₃);	Potential
Sodium Azide CAS# 26628-22-8		for cutaneous absorption	
IOELVs		Possibility of significant uptake through the skin; 0.1 mg	/m ³ TWA;
Sodium Azide CAS# 26628-22-8		0.3 mg/m ³ STEL	
NIOSH		None established	
Japan		None established	
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8.2 <u>Exposure controls</u>	
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	Lyophilised	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.4	Coefficien of Water/Oil	Not determined
-		Distribution	
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,	Not applicable	Viscosity	Not determined
Gas)		-	
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 <u>Reactivity</u>

No further relevant information available.

10.2 <u>Chemical Stability</u>

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 <u>Hazardous Decomposition Products</u>

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 -	No data available.
repeated exposure	NY 17 111
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 <u>Ecotoxicity</u>

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 <u>Results of PBT and vPvB assessment</u>

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 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

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 <u>Safety, health and environmental regulation/legislation specific for the substance or mixture</u>

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.	
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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	

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

<u>Canada</u>

This product does not meet WHMIS criteria for hazardous materials.

Not applicable
Sodium Azide
Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

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

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 H300 - Fatal if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany' s maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard





(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

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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INCUBATION BUFFER

INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 <u>Product identifier</u>

Product Name: Incubation Buffer

Catalog #: Component of OCFK07-PIIIP

1.2 Intended Use

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

1.3 <u>Company</u>

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 <u>Emergency telephone</u>

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 <u>Classification of the substance or mixture</u>

Product Description

Bleu; Clear; Liquid; OClassification according to EC 1272/2008Not classified as hazard(CLP/GHS)(CLP/GHS)Classification according to US-OSHANot classified as hazard(HCS 29 CFR 1910.1200) and UN GHS2012 and UN GHS

Mixture Bleu; Clear; Liquid; Odorless Not classified as hazardous per EC 1272/2008 (CLP/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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MATERIEL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide	< 0.05	Acute Tox. Oral 2	Acute Tox. Oral 2	2,8
CAS # 26628-22-8		Aquatic Acute 1	Aquatic Acute 1	
EINECS# 247-852-1		Aquatic Longterm 1	Aquatic Longterm 1	
Index # 011-004-00-7		H300; H400; H410	H300; H400; H410	
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 <u>Description of first aid measures</u>

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,
Skin Contact	obtain medical attention. 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
Ingestion	medical attention. 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 <u>Personal precaution, protective equipment and emergency procedures</u>

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 <u>Environmental Precautions</u>

Contain spill to prevent migration.

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

6.3 <u>Methods and material for containment and cleaning-up</u>

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 <u>Reference to other sections</u>

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 <u>Precautions for safe handling</u>

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 <u>Control parameters</u>

Exposure Limits

US OSHA ACGIH Sodium Azide CAS# 26628-22-8 DFG MAK Sodium Azide CAS# 26628-22-8 Ireland Sodium Azide CAS# 26628-22-8 IOELVs Sodium Azide CAS# 26628-22-8 IOELVs	 None established 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor) 0.4 mg/m³ Peak (inhalable fraction); 0.2 mg/m³ TWA MAK (inhalable fraction) 0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential for cutaneous absorption Possibility of significant uptake through the skin; 0.1 mg/m³ TWA; 0.3 mg/m³ STEL None established
Japan	None established
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8.2 <u>Exposure controls</u>	
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 Color	Liquid Blue	Specific Gravity (water = 1.0) Solubility:	1.00 @20°C
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
рН	7.2	Coefficien of Water/Oil	Not determined
		Distribution	
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,	Not applicable	Viscosity	Not determined
Gas)			
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 <u>Reactivity</u>

No further relevant information available.

10.2 <u>Chemical Stability</u>

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 <u>Hazardous Decomposition Products</u>

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 -	No data available.
repeated exposure	
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 <u>Ecotoxicity</u>

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 <u>Results of PBT and vPvB assessment</u>

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 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

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 <u>Safety, health and environmental regulation/legislation specific for the substance or mixture</u>

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.	
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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

<u>Canada</u>

This product does not meet WHMIS criteria for hazardous materials.

Not applicable	
Sodium Azide	
Product is exempt	

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

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

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 H300 - Fatal if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany' s maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard





(According to regulation (EC) 1907/2006 and amendments) Product Name: PIIIP IRMA Catalog #: OCFK07-PIIIP

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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