

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: AFP IRMA
 Catalog #: KIPB1441
 Kit Components: Coated tubes
 ¹²⁵I labeled-tracer
 Calibrators
 Controls
 Phosphate Buffer
 Wash Solution

1.2 Intended Use

For In Vitro Diagnostic Use. See product literature for details.
 This kit contains coated tubes that are considered articles and thereby exempt from SDS requirements.

1.3 Company

DIAsource ImmunoAssays S.A.
 Rue du Bosquet, 2
 B-1348 Louvain-la-Neuve
 Belgium
 Tel. Nr. +32 (0)10/84.99.11
 E-mail: tech.support@diasource.be

1.4 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 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

TRACER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tracer

Catalog #: Component of KIPB1441

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

2.2 Label elements

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

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

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

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



2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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

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

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 226628-22-8 EINECS# 247-852-1 Index # 011-004-00-7	< 0.1	T+; R28-32 N; R50/53	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 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 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/m³ Ceiling (as NaN₃); 0.1 ppm Ceiling (as Hydrazoic acid) (vapor)

Sodium Azide

CAS# 26628-22-8

DFG MAK

0.4 mg/m³ Peak (inhalable fraction); 0.2 mg/m³ TWA MAK (inhalable fraction)

Sodium Azide

CAS# 26628-22-8

Ireland

0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential for cutaneous absorption

Sodium Azide

CAS# 26628-22-8

IOELVs

Possibility of significant uptake through the skin; 0.1 mg/m³ TWA; 0.3 mg/m³ 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)	1.02 @20°C
Color	Red	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.2	Coefficien of Water/Oil	Not determined
		Distribution	
Freezing Point	Not applicable	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 applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
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.
Skin/ Respiratory 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 67/548/EEC Annex I.
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 <i>Oncorhynchus mykiss</i> : 0.8 mg/L; 96 h LC50 <i>Lepomis macrochirus</i> : 0.7 mg/L; 96 h LC50 <i>Pimephales promelas</i> : 5.46 mg/L [flow-through]
Microtox	Not determined for the product.
Water Flea	Not determined for the product.
Fresh Water Algae	Not determined for the product.

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



MATERIEL SAFETY DATA SHEET

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

Product Name: AFP IRMA

Catalog #: KIPB1441

NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazard					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

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

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

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration.
Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration.
1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration
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

Edetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

California Proposition 65

Acetaldehyde, Ethylene Oxide, 1,4-Dioxane, Neomycin Sulfate, Iodine 125 have 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 some chemicals known to the State of California to cause cancer.

Massachusetts MSL

Edetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Edetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Edetic Acid is listed.

**MATERIEL SAFETY DATA SHEET**

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

Product Name: AFP IRMA

Catalog #: KIPB1441

Acetaldehyde is listed.
 Ethylene Oxide is listed.
 1,4-Dioxane is listed.
 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	Acetaldehyde Ethylene Oxide 1,4-Dioxane Sodium Azide
Ingredient with unknown toxicological properties	Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 2 Reactivity with water: 0 Contact: 2	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
Hazard Class, hazard statements and risk phrase description from section 3 N - Dangerous for the environment T+ - Very toxic R28 Very toxic if swallowed. R32 Contact with acids liberates very toxic gas. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. 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.

CALIBRATORS

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Calibrators

Catalog #: Component of KIPB1441

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

2.2 Label elements

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

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

2.3 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.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 226628-22-8 EINECS# 247-852-1 Index # 011-004-00-7	< 0.1	T+; R28-32 N; R50/53	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 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 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.
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
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8.1 Control parameters
Exposure Limits

US OSHA	None established
ACGIH	0.29 mg/m ³ Ceiling (as NaN ₃); 0.1 1 ppm Ceiling (as Hydrazoic acid) (vapor)
Sodium Azide CAS# 26628-22-8	
DFG MAK	0.4 mg/m ³ Peak (inhalable fraction); 0.2 mg/m ³ TWA MAK (inhalable fraction)
Sodium Azide CAS# 26628-22-8	
Ireland	0.1 mg/m ³ TWA (as NaN ₃); 0.3 mg/m ³ STEL (as NaN ₃); Potential for cutaneous absorption
Sodium Azide CAS# 26628-22-8	
IOELVs	Possibility of significant uptake through the skin; 0.1 mg/m ³ TWA; 0.3 mg/m ³ STEL
Sodium Azide CAS# 26628-22-8	
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.02 @20°C
Color	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.4	Coefficien of Water/Oil	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, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
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.
Skin/ Respiratory sensitization	No data available.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration Hazard	No data available.
Other information	This product contains material of 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. PBT: Not applicable, vPvB: Not applicable.

12.5 Results of PBT and vPvB assessment

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

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

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

Canada

This product 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

<p>DIAsource ImmunoAssays Safety Rating</p>	<p>Flammability: 0 Health: 1 Reactivity with water: 0 Contact: 1</p>	<p><u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe</p>
<p>Hazard Class, hazard statements and risk phrase description from section 3 N - Dangerous for the environment T+ - Very toxic R28 Very toxic if swallowed. R32 Contact with acids liberates very toxic gas. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. 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.</p>		

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany' s maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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

Notification:

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

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

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CONTROLS

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Controls

Catalog #: Component of KIPB1441

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

2.2 Label elements

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

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

2.2.2 Labeling according to directive 98/79/EC

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Hazardous Ingredients: None

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.
Combustion products may contain minute amounts of mercury.

Hazardous Combustion Products: No combustion products posing significant hazards are expected from this product.

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 and animal 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.

Carefully sweep up spilled material and place in a container suitable for disposal.
Avoid generating dust.

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 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	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 – Liquid after reconstitution	Specific Gravity (water = 1.0)	1.02 @20°C
Color	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.4	Coefficien of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
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

No further relevant information available.

10.4 Conditions to Avoid

Avoid contact with incompatible materials.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients	Not applicable
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
Skin/ Respiratory 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 materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Fresh Water Species	No information available
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

No further relevant information available.

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.

This product contains a low level (<0.05%) of Thimerosal. Specific federal, state, and local regulations for disposal of mercury compounds may apply.

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

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

No ingredients listed.

California Proposition 65

Thimerosal has been identified by the State of California to cause reproductive harm. 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.

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

Massachusetts MSL

No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK

No ingredients listed.

EU regulations

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

Water Hazard Class (Germany)

WGK 1, low water endangering

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

No ingredients listed.

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

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

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Thimerosal

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

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:

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

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

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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PHOSPHATE BUFFER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Phosphate Buffer

Catalog #: Component of KIPB1441

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: tech.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	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 EC Directives 1999/45/EC and 67/548/EEC	Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label elements

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

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

2.3 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.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 226628-22-8 EINECS# 247-852-1 Index # 011-004-00-7	< 0.1	T+; R28-32 N; R50/53	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 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 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.
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); 0.1 1 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)	1.05 @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 applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
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 (a aqueous solution).

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide
CAS# 26628-22-8

Primary Routes of Exposure

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

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation Serious eye damage / eye irritation Skin/ Respiratory sensitization

No data available.
No data available.
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 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

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**

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration.

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration.

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration.

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

Edetic Acid is listed.

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde, Ethylene Oxide, 1,4-Dioxane, Neomycin Sulfate have 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

thefollowing warning:

WARNING: This product contains some chemicals known to the State of California to cause cancer.

Massachusetts MSL

Edetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Edetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Edetic Acid is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

EU regulations

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

REACH 1907/2006 EC - Annex XIV - No ingredients listed.
list of substances subject to authorization

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

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN	Not applicable
Ingredients on Ingredient Disclosure List	Acetaldehyde Ethylene Oxide 1,4-Dioxane Sodium Azide
Ingredient with unknown toxicological properties	Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

DIASource ImmunoAssays Safety Rating	Flammability: 0 Health: 1 Reactivity with water: 0 Contact: 1	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
<p>Hazard Class, hazard statements and risk phrase description from section 3</p> <p>N - Dangerous for the environment T+ - Very toxic R28 Very toxic if swallowed. R32 Contact with acids liberates very toxic gas. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. 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.</p> <p>Abbreviations and Acronyms</p> <p>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%</p>		

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



MATERIEL SAFETY DATA SHEET

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

Product Name: AFP IRMA

Catalog #: KIPB1441

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.

WASH SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Wash Solution

Catalog #: Component of KIPB1441

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: tech.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	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 EC Directives 1999/45/EC and 67/548/EEC	Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Toxic to Reproductive Category 1

2.2 Label elements

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

Hazardous Ingredients

Boric Acid
Sodium Borate Decahydrate

Pictogram



Signal Word
 DANGER

Hazard Statements

H360 May damage fertility or the unborn child.

Precautionary Statements

- P201 Obtain special instructions before use.
 - P280 Wear protective gloves, protective clothing and eye/face protection.
 - P308+P313 IF exposed or concerned: Get medical advice/attention.
 - P405 Store locked up.
 - P501 Dispose of contents/container in accordance with local/national regulations
- Product label will display most significant precautionary 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

Mixture

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Borate Decahydrate CAS # 1303-96-4 EINECS# 237-560-2 Index # 005-011-01-1	0.1-0.3	T ;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
Boric Acid CAS # 10043-35-3 EINECS# 233-139-2 Index # Not available	0.1-0.3	T ;R60-61 Repr. Cat. 2	Repr. 1B H360	Acute Tox. Dermal 5 Acute Tox. Oral 5 Repr. 1B Skin Irrit. 3 H303; H313; H316; H360	SVHC
SVHC - Substance of very high concern					

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, flush with copious amounts of 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

May damage fertility or the unborn child.
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

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: Observe general safety guidelines for protection; avoid eye and skin contact. 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: Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Use good laboratory procedures; avoid eye and skin contact.
Avoid inhaling, ingesting, and contact with eyes and skin.

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

Sodium Borate Decahydrate

CAS# 1303-96-4

6 mg/m³ STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2 mg/m³ TWA (inhalable fraction) (listed under Borate compounds, inorganic)

Boric Acid

CAS# 10043-35-3

6 mg/m³ STEL (inhalable fraction) (listed under Borate compounds, inorganic); 2mg/m³ TWA (inhalable fraction) (listed under Borate compounds, inorganic)

DFG MAK

Boric Acid

CAS# 10043-35-3

10 mg/m³ Peak (as B) (inhalable fraction); 10 mg/m³ TWA MAK (inhalable fraction) (as B)

Ireland

Sodium Borate Decahydrate

CAS# 1303-96-4

5 mg/m³ TWA

IOELVs

None established

NIOSH

Sodium Borate Decahydrate

CAS# 1303-96-4

5 mg/m³ TWA

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. 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 @20°C
Color	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	8.3	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

No further relevant information available.

10.4 Conditions to Avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

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

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Toxicity Data for Hazardous

Ingredients

Sodium Borate Decahydrate
CAS# 1303-96-4

Oral LD50 Rat 2660 mg/kg

Boric Acid
CAS# 10043-35-3

Oral LD50 Rat 2660 mg/kg; Inhalation LC50 Rat >0.16 mg/L 4 h; Dermal LD50 Rabbit >2000 mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

No data available.

Serious eye damage / eye irritation

No data available.

Skin/ Respiratory 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

May damage fertility or the unborn child.

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

No further relevant information available.

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Fresh Water Species

No information available

Microtox

No information available

Water Flea

Boric Acid
CAS# 10043-35-3

48 h EC50 Daphnia magna: 1 15 - 153 mg/L

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

No further relevant information available

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.

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

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

No ingredients listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Sodium Borate Decahydrate is listed.

New Jersey Dept. of Health RTK List

Sodium Borate Decahydrate is listed.

Pennsylvania RTK

Sodium Borate Decahydrate is listed.

**MATERIEL SAFETY DATA SHEET**

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

Product Name: AFP IRMA

Catalog #: KIPB1441

EU regulations

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

Water Hazard Class (Germany) WGK 1, low water endangering**REACH 1907/2006 EC - Annex XIV -** No ingredients listed.**list of substances subject to authorization****According to EC Directives (1999/45/EC and 67/548 EEC)** Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)**Canada**

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable**Ingredients on Ingredient Disclosure List** Sodium Borate Decahydrate

Boric Acid

Ingredient with unknown toxicological properties Product is exempt**15.2 Chemical Safety Assessment**

A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.***16 OTHER INFORMATION**

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 2 Reactivity with water: 0 Contact: 2	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
Hazard Class, hazard statements and risk phrase description from section 3		
T - Toxic Repr. Cat. 2 - Toxic for Reproduction Category 2 R60 May impair fertility. R61 May cause harm to unborn child. Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5 Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5 Skin Irrit. 3 - Skin Irritation Category 3 Repr. 1B - Toxic to Reproductive Category 1B H303 - May be harmful if swallowed H313 - May be harmful In contact with skin H316 - Causes mild skin irritation. H360 - May damage fertility or the unborn child.		
Abbreviations and Acronyms		
ACGIH - American Conference of Governmental Industrial Hygienists ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany' s maximum exposure limit GHS - Globally Harmonized System		

HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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

Notification:

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

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

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MSDS established : 2019-10-30

Revision number : 3