

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

Product Name: ACTH IRMA

Catalog #: KIP0061

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 **Product identifier**

Product Name: ACTH IRMA

Catalog #: KIP0061

Kit Components: Coated tubes

125 I labeled-tracer
Tracer Buffer
Incubation Buffer
Reconstitution Solution
Calibrators (0 to 6)
Controls (1 and 2)
Washing Solution

1.2 Intended Use

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

1.3 Company

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.11 Centre Anti-Poisons (BE) 070 245 245 Please refer to your local Anti-Poison Center!

2 TRANSPORT INFORMATION

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Materi	al, excepted package	-limited quantity of m	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 Additional	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Information IATA ERG Code EmS	7L Not applicable	Not applicable F-I, S-S	Not applicable Not applicable	Not applicable Not applicable	Not applicable Not applicable

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2 rue du Bosquet

1348 - Louvain-la-Neuve Belgium

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

Product Name: ACTH IRMA

Catalog #: KIP0061

NAERG Code Not applicable Not applicable 161 Not applicable 161

Environmental

Hazard

Marine Polluant Not applicable No Not applicable Not applicable Not applicable

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

3 OTHER INFORMATION

3.1 **General Precautions:**

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

3.2 Other hazard

Tracer Contains material from bovine origin
Tracer Buffer Contains material from bovine origin
Incubation Buffer Contains material from bovine origin

This kit contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

CalibratorsContains material from human originControlsContains material from human origin

3.3 <u>Labeling of tube:</u>

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Each tube can only be used once

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Product Name: ACTH IRMA

Catalog #: KIP0061

TRACER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tracer

Catalog #: Component of KIP0061

1.2 <u>Intended Use</u>

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

1.3 Company

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.11 Centre Anti-Poisons (BE) 070 245 245 Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description In vitro diagnostic reagent

Red; Clear; Liquid; Odorless

Classification according to EC 1272/2008 Not classified as hazardous per EC 1272/2008

(CLP/GHS) (CLP/GHS)

Classification according to US-OSHA

Not classified as hazardous per US-OSHA HCS

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

2.2 <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.

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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

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

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Hazardous Ingredien	ts:	Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 26628-22-8 EINECS# 247-852-1 Index # 011-004-00-7	< 0.05	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2,8

^{2 -} Substance with Community workplace exposure limits

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

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.

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^{8 -} Present at concentration below the cut-off limits.

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5 FIRE FIGHTING MEASURES

Flammable properties: Nonflammable aqueous solution.

5.1 Extinguishing media

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

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards: No special Hazards determined.

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

5.3 Advice for fire fighters

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

5.4 Additional information

No further relevant information available.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

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

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

6.2 Environmental Precautions

Contain spill to prevent migration.

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

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

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

6.3 Methods and material for containment and cleaning-up

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

Radioactive material is subject to the regulations of each country.

Dispose of all waste material in accordance with local guidelines.

Reference to other sections

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Refer sections 8 and 13.

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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); 0.11 ppm Ceiling (as Hydrazoic acid)

Sodium Azide (vapor

CAS# 26628-22-8

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

Sodium Azide (inhalable fraction)

CAS# 26628-22-8

Ireland 0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential

Sodium Azide for cutaneous absorption

CAS# 26628-22-8

IOELVs Possibility of significant uptake through the skin; 0.1 mg/m³ TWA;

Sodium Azide 0.3 mg/m³ STEL

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.

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PHYSICAL AND CHEMICAL PROPERTIES

9.1 <u>Information on basic physical and chemical properties</u>

Physical State Color	Liquid Colorless	Specific Gravity (water = 1.0) Solubility:	1.00 @20°C
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pН	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 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

Printing date

10.6 <u>Hazardous Decomposition Products</u>

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



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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 Respiratory/skin sensitization

Carcinogenicity

No data available. No data available. No data available.

This product does not contain a reportable concentration

 $(\geq 0.1\%)$ of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC

regulation.

Germ cell mutagenicity **Reproductive Toxicity**

Specific target organ toxicity - single

exposure

Specific target organ toxicity -

repeated exposure **Aspiration hazard**

Other information

No data available.

This product contains material of animal origin and

should be considered as potentially capable of

transmitting infectious diseases.

ECOLOGICAL INFORMATION

12.1 Ecotoxicity

96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 **Fresh Water Species** 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 No information available Water Flea 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.

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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.

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	2910
Shipping Name	Radioactive Materia	al, excepted package-	imited quantity of ma	aterial	
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

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

Product Name: ACTH IRMA

Catalog #: KIP0061

EmS Not applicable F-I, S-S Not applicable Not applicable Not applicable Not applicable 161 Not applicable 161

Environmental

Hazard

Marine Polluant Not applicable No Not applicable Not applicable Not applicable

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

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

15 REGULATORY INFORMATION

15.1 <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.

CERCLA RG's, 40 CFR 302.4 California Proposition 65 Sodium Azide is listed.

Iodine 125 has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to

individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, DIAsource ImmunoAssays advises you of

the following warning:

WARNING: This product contains a chemical known to

the State of California to cause cancer.

Massachusetts MSL New Jersey Dept. of Health RTK List Pennsylvania RTK Sodium Azide is listed. Sodium Azide is listed. Sodium Azide is listed.

No ingredients listed.

EU regulations

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

REACH 1907/2006 EC - Annex XIV

- list of substances subject to

authorization



Canada

This product is exempt from WHMIS label and SDS requirements.

PIN 2910

Ingredients on Ingredient Disclosure Sodium Azide

List

Ingredient with unknown Product is exempt **toxicological properties**

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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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

Rescription
Service ImmunoAssays Safety
Reactivity with water: 0
Service ImmunoAssays Safety

Hazard Class, hazard statements and risk phrase description from section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

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

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

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

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

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

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

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

HCS - Hazard Communication Standard

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LC50 - Lethal Concentration, 50%

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LD50 - Lethal Dose, 50%

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



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Catalog #: KIP0061

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 INFORMA TION 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.

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Product Name: ACTH IRMA

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TRACER BUFFER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tracer Buffer

Catalog #: Component of KIP0061

1.2 Intended Use

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

1.3 Company

DIAsource ImmunoAssays S.A.

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E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23 Centre Anti-Poisons (BE) 070 245 245 Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description Mixture

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 N

Not classified as hazardous per EC 1272/2008

(CLP/GHS)

(CLP/GHS)

Classification according to US-OSHA

Not classified as hazardous per US-OSHA HCS

(HCS 29 CFR 1910.1200) and UN GHS

2012 and UN GHS

2.2 Label elements

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 of human origin and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

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COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

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

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

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.

If product enters eyes, wash eyes gently under running water for 15 minutes **Eve Contact**

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.

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek **Ingestion**

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.

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

Printing date

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

^{8 -} Present at concentration below the cut-off limits.

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Product Name: ACTH IRMA

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5.4 Additional information

No further relevant information available.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

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/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (as Hydrazoic acid)

Sodium Azide (vapor

CAS# 26628-22-8

CAS# 26628-22-8

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

Sodium Azide (inhalable fraction) *CAS# 26628-22-8*

Ireland 0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential

Sodium Azide for cutaneous absorption

IOELVs Possibility of significant uptake through the skin; 0.1 mg/m³ TWA;

Sodium Azide 0.3 mg/m³ STEL

CAS# 26628-22-8

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DIAsource ImmunoAssays S.A

2 rue du Bosquet



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

Product Name: ACTH IRMA

Catalog #: KIP0061

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	Solid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Red	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pН	6,0	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 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.

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DIAsource ImmunoAssays S.A

2 rue du Bosquet



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

Product Name: ACTH IRMA

Catalog #: KIP0061

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

Ingredients Dermal LD50 Rabbit 20 mg/kg

Sodium Azide CAS# 26628-22-8

Primary Routes of ExposureCommon 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/IrritationNo data available.Serious eye damage/eye irritationNo data available.Respiratory/skin sensitizationNo 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 Reproductive ToxicityNo data available. **Specific target organ toxicity - single**No data available.

exposure

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 Ecotoxicity

Fresh Water Species96 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]

MicrotoxNo information availableWater FleaNo information availableFresh Water AlgaeNo information available

12.2 Persistence and degradability

Not determined for the product.

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DIAsource ImmunoAssays S.A

2 rue du Bosquet

MATERIEL SAFETY DATA SHEET

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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 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

2/12/22

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

Us Federal and State Regulations

Printing date



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

Product Name: ACTH IRMA

Catalog #: KIP0061

SARA 313 Sodium Azide is subject to reporting requirements of

Section 313, Title III of SARA. 1.0 % de minimis

concentration.

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU regulations

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

REACH 1907/2006 EC - Annex XIV

No ingredients listed.

- list of substances subject to

authorization

Canada

This product does not meet WHMIS criteria for hazardous materials.

PIN Not applicable Ingredients on Ingredient Disclosure Sodium Azide

List

Ingredient with unknown Product is exempt

toxicological properties

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

	Flammability: 0	Code 0 - None
DIAsource ImmunoAssays Safety Rating	Health: 1 Reactivity with water: 0	1 = Slight
Kuting	(ontact: 1	2 = Caution 3 = Severe

Hazard Class, hazard statements and risk phrase description from section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

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

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

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

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

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

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

CLP - Classification, Labeling and Packaging

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2 rue du Bosquet



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

Product Name: ACTH IRMA

Catalog #: KIP0061

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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MATERIEL SAFETY DATA SHEET

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

Product Name: ACTH IRMA

Catalog #: KIP0061

INCUBATION BUFFER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 **Product identifier**

Product Name: Incubation Buffer

Catalog #: Component of KIP0061

1.2 Intended Use

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

1.3 Company

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23 Centre Anti-Poisons (BE) 070 245 245 Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

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

Product Description Mixture

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 Not classified as hazardous per EC 1272/2008

(CLP/GHS) (CLP/GHS)

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

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

2.2 Label elements

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

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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

See section 8 for available Occupational exposure limits

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.

If product enters eyes, wash eyes gently under running water for 15 minutes **Eye Contact**

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.

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**

Printing date

No further relevant information available.

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^{8 -} Present at concentration below the cut-off limits.

See Section 15 for additional regulatory information

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



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

Product Name: ACTH IRMA

Catalog #: KIP0061

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

6.2 Environmental Precautions

Contain spill to prevent migration.

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

6.3 Methods and material for containment and cleaning-up

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

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities

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

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

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

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 <u>Control parameters</u>

Exposure Limits

US OSHA None established

ACGIH 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (as Hydrazoic acid)

Sodium Azide (vapor)

CAS# 26628-22-8

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

Sodium Azide (inhalable fraction)

CAS# 26628-22-8

Ireland 0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential

Sodium Azide for cutaneous absorption

CAS# 26628-22-8

IOELVs Possibility of significant uptake through the skin; 0.1 mg/m³ TWA;

Sodium Azide 0.3 mg/m³ STEL

CAS# 26628-22-8

NIOSH None established Japan None established

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MATERIEL SAFETY DATA SHEET

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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	Solid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pН	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 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.

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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).

TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Toxicity Data for Hazardous Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg;

Ingredients Dermal LD50 Rabbit 20 mg/kg

Sodium Azide 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. No data available.

Skin Corrosion/Irritation 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. No data available. Specific target organ toxicity - single

exposure

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.

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]

No information available **Microtox** No information available Water Flea No information available Fresh Water Algae

12.2 Persistence and degradability

Not determined for the product.

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DIAsource ImmunoAssays S.A

2 rue du Bosquet

MATERIEL SAFETY DATA SHEET

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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 $18\,01\,03^*$ - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

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

15 REGULATORY INFORMATION

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

Us Federal and State Regulations

SARA 313

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



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

Product Name: ACTH IRMA

Catalog #: KIP0061

CERCLA RG's, 40 CFR 302.4 Sodium Azide is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Azide is listed.

New Jersey Dept. of Health RTK List Sodium Azide is listed.

Pennsylvania RTK Sodium Azide is listed.

EU regulations

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

REACH 1907/2006 EC - Annex XIV

No ingredients listed.

- list of substances subject to

authorization

Canada

This product does not meet WHMIS criteria for hazardous materials.

PIN Not applicable Ingredients on Ingredient Disclosure Sodium Azide

List

Ingredient with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating Flammability: 0 Health: 1 Reactivity with water: 0 Contact: 1 Code 0 = None 1 = Slight 2 = Caution 3 = Severe
--

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

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DIAsource ImmunoAssays S.A

2 rue du Bosquet

MATERIEL SAFETY DATA SHEET

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

Product Name: ACTH IRMA

Catalog #: KIP0061

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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2/12/22



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

Product Name: ACTH IRMA

Catalog #: KIP0061

RECONSTITUTION SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 **Product identifier**

Product Name: Reconstitution Solution
Catalog #: Component of KIP0061

1.2 Intended Use

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

1.3 Company

DIAsource ImmunoAssays S.A.

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B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23 Centre Anti-Poisons (BE) 070 245 245 Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

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

Product Description Mixture

Yellowish; Clear; Liquid; Odorless

Classification according to EC 1272/2008 Not classified as hazardous per EC 1272/2008

(CLP/GHS) (CLP/GHS)

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

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

2.2 Label elements

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

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2 rue du Bosquet



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

Product Name: ACTH IRMA

Catalog #: KIP0061

Hazardous Ingredier	its:	Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 26628-22-8 EINECS# 247-852-1 Index # 011-004-00-7	< 0.05	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2,8
2 Substance with Community	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	yyma limita		

^{2 -} Substance with Community workplace exposure limits

See section 8 for available Occupational exposure limits

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

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No further relevant information available.

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^{8 -} Present at concentration below the cut-off limits.

See Section 15 for additional regulatory information

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



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6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

6.2 Environmental Precautions

Contain spill to prevent migration.

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

6.3 Methods and material for containment and cleaning-up

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

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities

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

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

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

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 <u>Control parameters</u>

Exposure Limits

US OSHA None established

ACGIH 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (as Hydrazoic acid)

Sodium Azide (vapor)

CAS# 26628-22-8

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

Sodium Azide (inhalable fraction)

CAS# 26628-22-8

Ireland 0.1 mg/m³ TWA (as NaN₃); 0.3 mg/m³ STEL (as NaN₃); Potential

Sodium Azide for cutaneous absorption

CAS# 26628-22-8

IOELVs Possibility of significant uptake through the skin; 0.1 mg/m³ TWA;

Sodium Azide 0.3 mg/m³ STEL

CAS# 26628-22-8

NIOSH None established Japan None established

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DiaSource

MATERIEL SAFETY DATA SHEET

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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.

PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State Color	Liquid Colorless	Specific Gravity (water = 1.0) Solubility:	1.00 @20°C
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pН	8,0	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		

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.

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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).

TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Toxicity Data for Hazardous Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg;

Ingredients Dermal LD50 Rabbit 20 mg/kg

Sodium Azide 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. No data available. No data available.

Skin Corrosion/Irritation Serious eye damage/eye irritation 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. No data available. Specific target organ toxicity - single

exposure

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.

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]

No information available **Microtox** No information available Water Flea No information available Fresh Water Algae

12.2 Persistence and degradability

Not determined for the product.

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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 $18\,01\,03^*$ - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

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

15 REGULATORY INFORMATION

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

Us Federal and State Regulations

SARA 313

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



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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

Canada

This product does not meet WHMIS criteria for hazardous materials.

PIN Not applicable Ingredients on Ingredient Disclosure Sodium Azide

List

Ingredient with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 1 Reactivity with water: 0 Contact: 1	Code 0 = None 1 = Slight 2 = Caution 3 = Sayara
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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

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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:

Printing date

2/12/22

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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