

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Cyclosporine direct RIA

Catalog #: KIPB3679

Kit Components: Coated tubes
¹²⁵I labeled-tracer
 Calibrators
 Control Serum

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 TRANSPORT INFORMATION

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

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional Information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161

**Environmental
Hazard**

Marine Pollutant Not applicable No Not applicable Not applicable Not applicable

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

3 OTHER INFORMATION

3.1 Labeling of tube:

Each tube can only be used once



TRACER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tracer

Catalog #: Component of KIPB3679

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; Slight odor
Classification according to EC 1272/2008 (CLP/GHS)	Flammable Liquids, Category 3
Classification according to EC Directives 1999/45/EC and 67/548/EEC	F;R10
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Flammable Liquids, Category 3

2.2 Label elements

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

Hazardous Ingredients

Ethyl Alcohol

Pictogram**Signal Word**

WARNING

Hazard Statements

H226 Flammable liquid and vapour.

Precautionary Statements

P210 Keep away from heat, hot surfaces, and sparks. No smoking.

P233 Keep container tightly closed.

P240 Ground container and receiving equipment.

P241 Use explosion-proof electrical equipment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharge.

P280 Wear protective gloves, protective clothing and eye/face protection.

P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.

P370+P378 In case of fire: Use water spray for extinction.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/national regulations

2.2.2 According to 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.

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	US OSHA WHMIS	
Ethyl Alcohol CAS # 64-17-5 EINECS# 200-578-6 Index # 603-002-00-5	10 - 20	F; R11	Flam. Liq. 2 H225	Flam. Liq. 2 H225	
Ethylene Oxide CAS # 75-21-8 EINECS# 200-849-9 Index # 603-023-00-X	< 0.01	F+;R12 T;R45-46-6-23- 36/37/38 Carc. Cat. 2 Muta. Cat. 2	Acute Tox. Inhal. 3 Carc. 1B Eye Irrit. 2 Flam. Gas 1 Muta. 1B Press. Gas [CG] STOT SE 3 Skin Irrit. 2 H220; H280; H315; H319; H331; H335; H340; H350	Acute Tox. Inhal. 3 Carc. 1B Eye Irrit. 2 Flam. Gas 1 Muta. 1B Press. Gas [CG] STOT SE 3 Skin Irrit. 2 H220; H280; H315; H319; H331; H335; H340; H350	

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

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: Flammable liquid and vapor.

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

Ethyl Alcohol 1000 ppm TWA; 1900 mg/m³ TWA
CAS# 64-17-5

Ethylene Oxide 1 ppm TWA; 5 ppm STEL (see 29 CFR 1910.1047)
CAS# 75-21-8

ACGIH

Ethyl Alcohol 1000 ppm STEL
CAS# 64-17-5

Ethylene Oxide 1 ppm TWA
CAS# 75-21-8

DFG MAK

Ethyl Alcohol 1000 ppm Peak; 1920 mg/m³ Peak; 500 ppm TWA MAK; 960 mg/m³ TWA MAK
CAS# 64-17-5

Ethylene Oxide skin notation
CAS# 75-21-8

Ireland

Ethyl Alcohol 1000 ppm STEL
CAS# 64-17-5

Ethylene Oxide 5 ppm TWA; 10 mg/m³ TWA
CAS# 75-21-8

NIOSH

Ethyl Alcohol 3300 ppm IDLH (10% LEL); 1000 ppm TWA; 1900 mg/m³ TWA
CAS# 64-17-5

Ethylene Oxide 800 ppm IDLH; 0.1 ppm TWA (less than stated value); 0.18 mg/m³ TWA (less than stated value)
CAS# 75-21-8

Japan

Ethylene Oxide 1 ppm OEL; 1.8 mg/m³ OEL
CAS# 75-21-8

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	Slight odor	Organic	Not determined
pH	4.5	Coefficien of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not determined
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	36 (96.8°F)	Percent Volatiles	Not determined
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	Ethyl Alcohol 180 ppm geometric mean air odor threshold = (detectable); 100 ppm geometric mean air odor threshold = (recognizable)		
	Ethylene Oxide 420 ppm geometric mean air odor threshold = (detectable); 490 ppm geometric mean air odor threshold = (recognizable)		

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

Avoid exposure to heat and incompatible materials.

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

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**

Ethyl Alcohol
CAS# 64-17-5

Oral LD50 Rat 7060 mg/kg; Inhalation LC50 Rat 124.7 mg/L 4 h

Ethylene Oxide
CAS# 75-21-8

Oral LD50 Rat 72 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 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**Ethyl Alcohol
CAS# 64-17-5

96 h LC50 Oncorhynchus mykiss: 12.0 - 16.0 mL/L [static]; 96 h LC50 Pimephales promelas: >100 mg/L [static]; 96 h LC50 Pimephales promelas: 13400 - 15100 mg/L [flow-through]

Ethylene Oxide
CAS# 75-21-8

96 h LC50 Pimephales promelas: 73-96 mg/L

Microtox

No information available

Water FleaEthyl Alcohol
CAS# 64-17-5

48 h LC50 Daphnia magna: 9268 - 14221 mg/L; 24 h EC50 Daphnia magna: 10800 mg/L; 48 h EC50 Daphnia magna: 2 mg/L [Static]

Ethylene Oxide
CAS# 75-21-8

48 h LC50 Daphnia magna: 137 - 300 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.

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 06* - chemicals consisting of or containing dangerous substances. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

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

Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
UN/ID Number	2910	2910	2910	2910	PIN - 2910
Shipping Name	Radioactive Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Materials
Subsidiary Risk	None	None	None	None	None
Classification Code	Not applicable	Not applicable	Not applicable	None	Not applicable
Packing Group					
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional Information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161
Environmental Hazard					
Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable

Special Precautions for 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.

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

California Proposition 65

Ethyl Alcohol, Acetaldehyde, Ethylene Oxide, Iodine 125 and 1,4-Dioxane 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.

WARNING: Those products contain chemicals known to the State of California to cause cancer.

Massachusetts MSL

Ethyl Alcohol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

New Jersey Dept. of Health RTK List

Ethyl Alcohol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

Pennsylvania RTK

Ethyl Alcohol is listed.
Acetaldehyde is listed.
Ethylene Oxide is listed.
1,4-Dioxane is 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)**Canada**

This product is exempt from WHMIS label and SDS requirements.

PIN

2910

Ingredients on Ingredient Disclosure List

Ethyl Alcohol
Acetaldehyde
Ethylene Oxide
1,4-Dioxane

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: 3 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 Carc. Cat. 2 - Carcinogen Category 2 F - Highly flammable F+ - Extremely flammable Muta. Cat. 2 - Mutagen category 2 T - Toxic R11 Highly flammable. R12 Extremely flammable. R45 May cause cancer. R46 May cause heritable genetic damage. R6 Explosive with or without contact with air. R23 Toxic by inhalation. R36/37/38 Irritating to eyes, respiratory system and skin. Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3 Carc. 1B - Carcinogenicity Category 1B Eye Irrit. 2 - Eye Irritation Category 2 Flam. Gas 1 - Flammable Gases (including chemically unstable gases), Category 1 Flam. Liq. 2 - Flammable Liquids, Category 2 Press. Gas [CG] - Gases under pressure, Compressed Gas Muta. 1B - Germ Cell Mutagenicity Category 1B Skin Irrit. 2 - Skin Irritation Category 2 STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3 H220 - Extremely flammable gas. H225 - Highly flammable liquid and vapour. H280 - Contains gas under pressure; may explode if heated. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H331 - Toxic if inhaled. H335 - May cause respiratory irritation. H340 - May cause genetic defects. H350 - May cause cancer.		
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		

**MATERIEL SAFETY DATA SHEET**

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

Product Name: Cyclosporine direct RIA

Catalog #: KIPB3679

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 KIPB1138

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

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

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

4 FIRST AID MEASURES

4.1 Description of first aid measures

- Inhalation** If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.
- Eye Contact** If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.
- Skin Contact** In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.
- Ingestion** If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

Flammable properties: Nonflammable aqueous solution.

5.1 Extinguishing media

In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam.
 For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards: No special hazards determined.

Hazardous Combustion Products: No Combustible products posing significant hazards are expected from this product (a 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); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)
Sodium Azide CAS# 26628-22-8	
DFG MAK	0.4 mg/m ³ Peak (inhalable fraction); 0.2 mg/m ³ TWA MAK (inhalable fraction)
Sodium Azide CAS# 26628-22-8	
Ireland	0.1 mg/m ³ TWA (as NaN ₃); 0.3 mg/m ³ STEL (as NaN ₃); Potential for cutaneous absorption
Sodium Azide CAS# 26628-22-8	
IOELVs	Possibility of significant uptake through the skin; 0.1 mg/m ³ TWA; 0.3 mg/m ³ STEL
Sodium Azide CAS# 26628-22-8	
NIOSH	None established
Japan	None established

8.2 Exposure controls

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

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.02 @20°C
Color	Yellowish	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.4	Coefficien of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not 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	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; 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.
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 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

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

California Proposition 65

Acetaldehyde, Ethylene Oxide, Cyclosporine and 1,4-Dioxane 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, **WARNING:** Those products contain chemicals known to the State of California to cause cancer.

Massachusetts MSL

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

Pennsylvania RTK

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 (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 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
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

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CONTROLS

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Controls

Catalog #: Component of KIPB3679

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 Powder - 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).

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

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: 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 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.

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
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	Lyophilized Powder - 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 material of 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 California Proposition 65

No ingredients listed
Neomycin Sulfate, Cyclosporine and Thimerosal have 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.

**MATERIEL SAFETY DATA SHEET**

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

Product Name: Cyclosporine direct RIA

Catalog #: KIPB3679

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**

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

**MATERIEL SAFETY DATA SHEET**

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

Product Name: Cyclosporine direct RIA

Catalog #: KIPB3679

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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MSDS established : 2019-10-30

Revision number : 3