

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name:	Angiotensin I (PRA) IRMA
Catalog #:	KIP5361
Kit Components:	Coated tubes ¹²⁵ I labeled-tracer Dilution Buffer Enzymatic Inhibitor Calibrators (0 to 5) Control (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 Material, excepted package-limited quantity of material				
Hazard Class	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Materials
Subsidiary Risk Classification Code	None	None	None	None	None
Packing Group	Not applicable	Not applicable	Not applicable	None	Not applicable
Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional Information					
IATA ERG Code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG Code	Not applicable	Not applicable	161	Not applicable	161

TRACER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tracer
 Catalog #: Component of KIP5361

1.2 Intended Use

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

1.3 Company

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

1.4 Emergency telephone

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

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Red; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Skin Sensitization Category 1
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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

Danger symbol



Signal word

Warning

Product Identifier

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Danger

H317 May cause an allergic skin reaction.

Supplemental Hazard Information

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Prevention statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

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

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


Response statements

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

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

Storage statements

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Disposal statements

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

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:		Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS# Not available Index # Not available	<0.1	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; 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, rinse eyes gently with water as a precaution.
- Skin Contact** In case of skin contact, rinse with water as a precaution.
- Ingestion** If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

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 material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

6.2 Environmental Precautions

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 end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Red	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not applicable
pH	7.5	Coefficient of Water/Oil	Not determined
Freezing Point	Not determined	Distribution	
Boiling Point	Not determined	Autoignition Temp.	Not applicable
		Decomposition Temperature	Not determined

Flash Point	Not applicable	Percent Volatiles	Not determines
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

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

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

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

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Toxicity Data for Hazardous

Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

CAS # 55965-84-9

Oral LD50 Rat 53mg/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.

Acute Toxicity

Not classified based on available data.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

May cause an allergic skin reaction.

Carcinogenicity

This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by

Germ cell mutagenicity**Reproductive Toxicity****Specific target organ toxicity - single exposure****Specific target organ toxicity - repeated exposure****Aspiration hazard****Other information**

ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Not classified based on available data.

Not classified based on available data.

Not classified based on available data.

Not classified based on available data.

Not classified based on available data.

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

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Fresh Water Species

No information available

Microtox

No information available

Water Flea

No information available

Fresh Water Algae

No information available

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product Waste Disposal:

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal:

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06.
Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

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

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

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

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

15 REGULATORY INFORMATION

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

Us Federal and State Regulations

SARA 313	No ingredients listed
CERCLA (The Comprehensive Environmental Response, Compensation and Liability Act) 40 CFR 302.4	No ingredients listed
California Proposition 65	WARNING: This product can expose you to chemical which is known to the State of California to cause cancer and/or harm. For more information, go to www.P65Warnings.ca.gov
Chemical which is known to the State of California to cause cancer	Iodine 125 (CAS # 14158-31-7)
Chemical which is known to the State of California to cause development toxicity	No ingredients listed
	No ingredients listed

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed

Chemical which is known to the State of California to cause female reproductive toxicity

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

No ingredients listed.

- list of substances subject to authorization



Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out...

Some hazardous ingredients listed in Section 15 are below the cutoff of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

16 OTHER INFORMATION

DIASource ImmunoAssays Safety Rating	Flammability: 0 Health: 2 Reactivity with water: 1 Contact: 2	<u>Code</u> 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. Dermal 3 - Acute Toxicity Dermal, Category 3 Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 Skin Corr. 1B - Skin Corrosion Category 1B Skin Sens. 1 - Skin Sensitization Category 1 H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. 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 and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LD50 - Lethal Dose, 50%

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

Notification:

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

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

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CALIBRATORS

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Calibrators
 Catalog #: Component of KIP5361

1.2 Intended Use

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

1.3 Company

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

1.4 Emergency telephone

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

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Colorless; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Skin Sensitization Category 1
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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

Danger symbol



Signal word

Warning

Product Identifier

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Danger

H317 May cause an allergic skin reaction.

Supplemental Hazard Information

-

Prevention statements

P261 Avoid breathing vapours.
 P272 Contaminated work clothing should not be allowed out of the workplace.

Response statements

P280 Wear protective gloves, protective clothing and eye/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before use.
 P501 Dispose of contents/container in accordance with local/national regulations.

Storage statements -

Disposal statements -

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:		Hazard Classification of Pure Ingredients	
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS# Not available Index # Not available	<0.1	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; 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, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

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 material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

6.2 Environmental Precautions

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.

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities

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

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

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

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not applicable
pH	7.2	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not determines
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY**10.1 Reactivity**

No further relevant information available.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

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

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

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

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Toxicity Data for Hazardous****Ingredients**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

CAS # 55965-84-9

Oral LD50 Rat 53mg/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.

Acute Toxicity

Not classified based on available data.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

May cause an allergic skin reaction.

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

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity - single exposure

Not classified based on available data.

Specific target organ toxicity - repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other information

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

12 ECOLOGICAL INFORMATION**12.1 Ecotoxicity**

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

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods****Product Waste Disposal:**

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number

Not regulated for transportation

14.2 Shipping Name

Not regulated for transportation

14.3 Hazard Class

Not regulated for transportation

14.4 Packing Group

Not regulated for transportation

14.5 Environmental Hazards

Not regulated for transportation

14.6 Special Precautions for user

None

14.7 Transport in bulk according to Annex II of MARPOL 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**

No ingredients listed

CERCLA (The Comprehensive Environmental Response, Compensation and Liability Act) 40 CFR 302.4

No ingredients listed

California Proposition 65**WARNING:** This product can expose you to chemical which is known to the State of California to cause cancer and/or harm. For more information, go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed

Chemical which is known to the State of California to cause development toxicity

No ingredients listed

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed

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 No ingredients listed.

- list of substances subject to authorization
Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out...

Some hazardous ingredients listed in Section 15 are below the cutoff of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.
16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 2 Reactivity with water: 1 Contact: 2	<u>Code</u> 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. Dermal 3 - Acute Toxicity Dermal, Category 3 Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 Skin Corr. 1B - Skin Corrosion Category 1B Skin Sens. 1 - Skin Sensitization Category 1 H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. 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 and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations.		

UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LD50 - Lethal Dose, 50%

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

Notification:

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

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

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CONTROL

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Control
 Catalog #: Component of KIP5361

1.2 Intended Use

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

1.3 Company

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

1.4 Emergency telephone

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

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Colorless; Clear; Liquid; Pungent
Classification according to EC 1272/2008 (CLP/GHS)	Skin Sensitization Category 1
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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

Danger symbol



Signal word

Warning

Product Identifier

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Danger

H317 May cause an allergic skin reaction.

Supplemental Hazard Information

-

Prevention statements

P261 Avoid breathing vapours.
 P272 Contaminated work clothing should not be allowed out of the workplace.

Response statements

P280 Wear protective gloves, protective clothing and eye/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before use.
 P501 Dispose of contents/container in accordance with local/national regulations.

Storage statements -

Disposal statements -

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:		Hazard Classification of Pure Ingredients	
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS# Not available Index # Not available	<0.1	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; 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, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

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 material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

6.2 Environmental Precautions

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.

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities

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

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

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

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not applicable
pH	7.2	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not determines
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY**10.1 Reactivity**

No further relevant information available.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

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

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

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

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Toxicity Data for Hazardous Ingredients**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)
CAS # 55965-84-9

Oral LD50 Rat 53mg/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.

Acute Toxicity

Not classified based on available data.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

May cause an allergic skin reaction.

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

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity - single exposure

Not classified based on available data.

Specific target organ toxicity - repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other information

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

12 ECOLOGICAL INFORMATION**12.1 Ecotoxicity**

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

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods****Product Waste Disposal:**

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number

Not regulated for transportation

14.2 Shipping Name

Not regulated for transportation

14.3 Hazard Class

Not regulated for transportation

14.4 Packing Group

Not regulated for transportation

14.5 Environmental Hazards

Not regulated for transportation

14.6 Special Precautions for user

None

14.7 Transport in bulk according to Annex II of MARPOL 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**

No ingredients listed

CERCLA (The Comprehensive Environmental Response, Compensation and Liability Act) 40 CFR 302.4

No ingredients listed

California Proposition 65**WARNING:** This product can expose you to chemical which is known to the State of California to cause cancer and/or harm. For more information, go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed

Chemical which is known to the State of California to cause development toxicity

No ingredients listed

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed

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 No ingredients listed.

- list of substances subject to authorization

Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out...

Some hazardous ingredients listed in Section 15 are below the cutoff of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 2 Reactivity with water: 1 Contact: 2	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
<p>Hazard Class, hazard statements and risk phrase description from section 3</p> <p>Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3 Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 Skin Corr. 1B - Skin Corrosion Category 1B Skin Sens. 1 - Skin Sensitization Category 1 H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.</p> <p>Abbreviations and Acronyms</p> <p>ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations.</p>		

UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LD50 - Lethal Dose, 50%

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

Notification:

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

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

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DILUTION BUFFER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Dilution Buffer
 Catalog #: Component of KIP5361

1.2 Intended Use

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

1.3 Company

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

1.4 Emergency telephone

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

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product Description	Colorless; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Skin Sensitization Category 1
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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

Danger symbol



Signal word

Warning

Product Identifier

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Danger

H317 May cause an allergic skin reaction.

Supplemental Hazard Information

-

Prevention statements

P261 Avoid breathing vapours.
 P272 Contaminated work clothing should not be allowed out of the workplace.

Response statements

P280 Wear protective gloves, protective clothing and eye/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before use.
 P501 Dispose of contents/container in accordance with local/national regulations.

Storage statements -

Disposal statements -

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:		Hazard Classification of Pure Ingredients	
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS# Not available Index # Not available	<0.1	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; 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, rinse eyes gently with water as a precaution.

Skin Contact In case of skin contact, rinse with water as a precaution.

Ingestion If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

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 material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.

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

6.2 Environmental Precautions

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.

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities

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

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

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

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (water = 1.0)	1.00 @20°C
Color	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not applicable
pH	6,0	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not determines
Evaporate Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY**10.1 Reactivity**

No further relevant information available.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

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

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

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

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Toxicity Data for Hazardous****Ingredients**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

CAS # 55965-84-9

Oral LD50 Rat 53mg/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.

Acute Toxicity

Not classified based on available data.

Skin Corrosion/Irritation

Not classified based on available data.

Serious eye damage/eye irritation

Not classified based on available data.

Respiratory/skin sensitization

May cause an allergic skin reaction.

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

Not classified based on available data.

Reproductive Toxicity

Not classified based on available data.

Specific target organ toxicity - single exposure

Not classified based on available data.

Specific target organ toxicity - repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other information

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

12 ECOLOGICAL INFORMATION**12.1 Ecotoxicity**

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

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods****Product Waste Disposal:**

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID Number

Not regulated for transportation

14.2 Shipping Name

Not regulated for transportation

14.3 Hazard Class

Not regulated for transportation

14.4 Packing Group

Not regulated for transportation

14.5 Environmental Hazards

Not regulated for transportation

14.6 Special Precautions for user

None

14.7 Transport in bulk according to Annex II of MARPOL 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**

No ingredients listed

CERCLA (The Comprehensive Environmental Response, Compensation and Liability Act) 40 CFR 302.4

No ingredients listed

California Proposition 65**WARNING:** This product can expose you to chemical which is known to the State of California to cause cancer and/or harm. For more information, go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed

Chemical which is known to the State of California to cause development toxicity

No ingredients listed

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed

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 No ingredients listed.

- list of substances subject to authorization
Canada

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out...

Some hazardous ingredients listed in Section 15 are below the cutoff of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.
16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 0 Health: 2 Reactivity with water: 1 Contact: 2	<u>Code</u> 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. Dermal 3 - Acute Toxicity Dermal, Category 3 Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3 Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1 Skin Corr. 1B - Skin Corrosion Category 1B Skin Sens. 1 - Skin Sensitization Category 1 H301 - Toxic if swallowed. H311 - Toxic in contact with skin. H314 - Causes severe skin burns and eye damage. H317 - May cause an allergic skin reaction. H331 - Toxic if inhaled. 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 and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations.		

UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LD50 - Lethal Dose, 50%

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

Notification:

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

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

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ENZYMATIC SOLUTION**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY****1.1 Product identifier**

Product Name: Enzymatic Solution
Catalog #: Component of KIP5361

1.2 Intended Use

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

1.3 Company

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

1.4 Emergency telephone

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

2 HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture**

Product Description	Colorless; Clear; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Flammable liquids Category 2
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

2.2 Label elements according to the regulation (EC) n°1272/2008 (CLP) and its amendments**Danger symbol**

Signal word Danger
Product Identifier Ethanol

Danger H225 Highly flammable liquid and vapor
Supplemental Hazard Information -

Prevention statements P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P240 Ground and bond container and receiving equipment.

P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.

P242 Use non-sparking tools

Response statements -

Storage statements -

Disposal statements -

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

See Section 11 Toxicological Information for more detailed health information.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:		Hazard Classification of Pure Ingredients	
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS
Ethanol CAS # 64-17-5 EINECS# 200-578-6 Index # 603-002-00-5	<98	Flammable liquids 2 H225	Flammable liquids 2 H225

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

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

4 FIRST AID MEASURES

4.1 Description of first aid measures

- 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, rinse eyes gently with water as a precaution.
- Skin Contact** In case of skin contact, rinse with water as a precaution.
- Ingestion** If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Combustible.

Pay attention to flashback.

Vapors are heavier than air and may spread along floors.

Development of hazardous combustion gases or vapours possible in the event of fire.

Forms explosive mixtures with air at ambient temperatures.

5.3 Advice for fire fighters

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

5.4 Additional information

Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental Precautions

Do not let product enter drains. Risk of explosion.

6.3 Methods and material for containment and cleaning-up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemisorb®). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Refer sections 8 and 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on protection against fire and explosion: Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures: Change contaminated clothing. Wash hands after working with substance.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

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

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

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

7.3 Specific end uses

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

US OSHA	None established
ACGIH	None established
DFG MAK	None established
Ireland	None established

IOELVs	None established
NIOSH	None established
Japan	None established

8.2 Exposure controls

Engineering Controls	Ingredients with workplace control parameters.
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)	0,79 @20°C
Color	Colorless	Solubility:	
Transparency	Clear	Water	Miscible
Odor	Pungent	Organic	Not applicable
pH	7,0	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	455°C @1013 hPa
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	13°C	Percent Volatiles	Not determines
Evaporate Rate	Not determined	Vapor Pressure	0,57 hPa @19,6°C
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor threshold	Not applicable		

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

Vapors may form explosive mixture with air.

10.2 Chemical Stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid

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

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous Decomposition Products

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

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Primary Routes of Exposure	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute Toxicity	LD50 Oral - Rat - male and female - 10.470 mg/kg (OECD Test Guideline 401) LC50 Inhalation - Rat - male and female - 4 h - 124,7 mg/l - vapor. (OECD Test Guideline 403)
Skin Corrosion/Irritation	Skin - Rabbit Result: No skin irritation - 24 h. (OECD Test Guideline 404)
Serious eye damage/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Maximization Test - Guinea pig Result: negative (OECD Test Guideline 406)
Carcinogenicity	Not classified based on available data.
Germ cell mutagenicity	Not classified based on available data.
Reproductive Toxicity	Not classified based on available data.
Specific target organ toxicity - single exposure	Not classified based on available data.
Specific target organ toxicity - repeated exposure	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
Other information	Not classified based on available data.

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 an approved waste-disposal company for information.

Package disposal:

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

14 TRANSPORT INFORMATION

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

14.1 UN/ID Number

Not regulated for transportation

14.2 Shipping Name

Not regulated for transportation

14.3 Hazard Class

Not regulated for transportation

14.4 Packing Group

Not regulated for transportation

14.5 Environmental Hazards

Not regulated for transportation

14.6 Special Precautions for user

None

14.7 Transport in bulk according to Annex II of MARPOL 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**

No ingredients listed

CERCLA (The Comprehensive Environmental Response, Compensation and Liability Act) 40

No ingredients listed

CFR 302.4**California Proposition 65****WARNING:** This product can expose you to chemical which is known to the State of California to cause cancer and/or harm. For more information, go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

No ingredients listed

Chemical which is known to the State of California to cause development toxicity

No ingredients listed

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed

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

No ingredients listed.

- list of substances subject to authorization**Canada**

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out...

Some hazardous ingredients listed in Section 15 are below the cutoff of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

16 OTHER INFORMATION

DIAsource ImmunoAssays Safety Rating	Flammability: 2 Health: 1 Reactivity with water: 1 Contact: 1	<u>Code</u> 0 = None 1 = Slight 2 = Caution 3 = Severe
Hazard Class, hazard statements and risk phrase description from section 3 Flammable liquid, Category 2 H225 Highly flammable liquid and vapor. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P240 Ground and bond container and receiving equipment. P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment. P242 Use non-sparking tools.		
Abbreviations and Acronyms ACGIH - American Conference of Governmental Industrial Hygienists ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit GHS - Globally Harmonized System HCS - Hazard Communication Standard IARC - International Agency for Research on Cancer IATA DGR - International Air Transport Association Dangerous Goods Regulation ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods IOELVs - European Unions' Indicative Occupational Exposure Limit Values NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent bioaccumulative and toxic substances SARA - Superfund Amendments and Reauthorization Act TDG - Canadian Transportation Of Dangerous Goods Regulations. UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation WHMIS - Workplace Hazardous Material Information System vPvB - Very persistent and very bioaccumulative substances LD50 - Lethal Dose, 50%		

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

Notification:

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

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

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MSDS established : 2022-07-14

Revision number : 3