

The following safety data sheets are valid for the Demeditec ELISA Kits listed in the table below:

Article number	Trade Name
DE2475	CPV (Canine Parvo Virus) IgG ELISA
DE2476	CPV (Canine Parvo Virus) IgM ELISA

Each ELISA product contains the following components:

P/N	Component name	Component classification according to Regulation (EC) no.1272/2008 [CLP]
10060001	Microplate	Not classified
10060000	Strip holder	Not classified
10060002	ELISA buffer	Not classified
10060003	HRPO conjugated anti-species antibodies	Not classified
10060007	Antigen	Not classified
10060004	Positive Control	Not classified
10060005	Negative Control	Not classified
00000004	Concentrated Wash Solution	Not classified *
00000001	Substrate A	Not classified
00000002	Substrate B	Not classified
00000003	Stop Solution	Danger – H314
00000005	Plastic cover seal	Not classified

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS is in accordance with Annex II of the COMMISSION REGULATION (EU) No 2015/830 of 01 June 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, authorization and Restriction of Chemicals (REACH).

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Microplate (10060001)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH	Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2	Fax: +49-(0)431 / 71922-55
D-24145 Kiel	E-Mail: info@demeditec.de
Germany	http: //www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
No labelling required.

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:
To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation:	Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion:	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media:	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard:	Not flammable.
Explosion hazard:	Product is not explosive.
Hazardous decomposition products in case of fire:	Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures:	Evacuate unnecessary personnel.
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6.1.2 For emergency responders

Protective equipment:	Equip clean-up crew with proper protection.
Emergency procedures:	Ventilate area.

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:	Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products:	Strong bases. Strong acids.
Incompatible materials:	Sources of ignition. Direct sunlight.
Storage temperature:	2 - 8 °C
Heat and ignition sources:	Conditions to be avoided.
Prohibitions on mixed storage:	Heat sources. Direct sunlight.
Special rules on packaging:	Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Personal protective equipment:	Avoid all unnecessary exposure.
Materials for protective clothing:	Wear suitable protective clothing
Hand protection:	Wear protective gloves
Eye protection:	Chemical goggles or safety glasses
Respiratory protection:	Respiratory protection equipment not absolutely necessary



Environmental exposure controls:	Avoid release to the environment.
Other information:	Do not eat, drink or smoke during use.

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Solid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Insoluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified
Skin corrosion/irritation:	Not classified; based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Not classified; based on available data, the classification criteria are not met.
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not classified; based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No additional information available

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

No additional information available

12.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal recommendations:	Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials:	Avoid release to the environment.

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) nwg, Non-hazardous to water (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:

Trade name: Microplate
Product number: Valid for ELISA products listed in the table on page 1

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:

None of the components are listed

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

Trade name: ELISA Buffer
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: ELISA Buffer (10060002)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Precautionary statements (CLP): P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

Other hazards not contributing to the classification:

The product contains inactivated (BSE free) purified albumin: ≥99%.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

Trade name: ELISA Buffer
Product number: Valid for ELISA products listed in the table on page 1

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation:	Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion:	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media:	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard:	Not flammable.
Explosion hazard:	Product is not explosive.
Hazardous decomposition products in case of fire:	Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection.

Trade name: ELISA Buffer
Product number: Valid for ELISA products listed in the table on page 1

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.

Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct sunlight.

Storage temperature: 2 - 8 °C

Heat and ignition sources: Conditions to be avoided.

Prohibitions on mixed storage: Heat sources. Direct sunlight.

Special rules on packaging: Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Personal protective equipment: Avoid all unnecessary exposure.

Materials for protective clothing: Wear suitable protective clothing

Hand protection: Wear protective gloves

Eye protection: Chemical goggles or safety glasses

Trade name: ELISA Buffer
Product number: Valid for ELISA products listed in the table on page 1

Respiratory protection: Respiratory protection equipment not absolutely necessary



Environmental exposure controls: Avoid release to the environment.

Other information: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Pale yellow
Odour:	Odourless
Odour threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

Trade name: ELISA Buffer
Product number: Valid for ELISA products listed in the table on page 1

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified
Skin corrosion/irritation:	Not classified; based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Not classified; based on available data, the classification criteria are not met.
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not classified; based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No additional information available

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Additional information: Avoid release to the environment

Trade name: ELISA Buffer
Product number: Valid for ELISA products listed in the table on page 1

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

Trade name:	ELISA Buffer
Product number:	Valid for ELISA products listed in the table on page 1

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:

None of the components are listed

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: HRPO conjugated anti-species antibodies (10060003)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Precautionary statements (CLP): P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

Other hazards not contributing to the classification:

The product contains inactivated dog/cat material free of known diseases. It's purified monoclonal antibody produced in tissue culture buffer with albumin.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tris(hydroxymethyl)-aminomethane	(CAS No) 77-86-1 (EC no) 201-064-4	0.25 - 0.5	Not classified
Bronidox L Cognis	(CAS No) 30007-47-7 (EC no) 250-001-7	0.25 - 0.5	Skin Corr. 1B, H314 Aquatic Chronic 2, H411

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow breathing of fresh air. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.

Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct sunlight.

Storage temperature: 2 - 8 °C

Heat and ignition sources: Conditions to be avoided.

Prohibitions on mixed storage: Heat sources. Direct sunlight.

Special rules on packaging: Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Personal protective equipment: Avoid all unnecessary exposure.

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

Materials for protective clothing: Wear suitable protective clothing
Hand protection: Wear protective gloves
Eye protection: Chemical goggles or safety glasses
Respiratory protection: Respiratory protection equipment not absolutely necessary



Environmental exposure controls: Avoid release to the environment.
Other information: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	≈ 6.4
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified

Tris(hydroxymethyl)-aminomethane (77-86-1)	
LD50 oral rat	> 3000 mg/kg
LD50 dermal rat	> 5000 mg/kg
Bronidox L Cognis (30007-47-7)	
LD50 oral rat	> 2000 - 5000 mg/kg

Skin corrosion/irritation:	Not classified; based on available data, the classification criteria are not met. pH: ≈ 6.4 (6 - 8)
Serious eye damage/irritation:	Not classified; based on available data, the classification criteria are not met. pH: ≈ 6.4 (6 - 8)
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not classified; based on available data, the classification criteria are not met.

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

SECTION 12: ECOLOGICAL INFORMATION**12.1 Toxicity**

Tris(hydroxymethyl)-aminomethane (77-86-1)	
EC50 Daphnia 1	980 mg/L 48 h
NOEC chronic algae	100 mg/L 72 h
Bronidox L Cognis (30007-47-7)	
LC50 fish 1	≈ 5 (1 - 10) mg/L
EC50 other aquatic organisms 1	≈ 5 (1 - 10) mg/L

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 2, hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

Trade name: HRPO conjugated anti-species antibodies
Product number: Valid for ELISA products listed in the table on page 1

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:

None of the components are listed

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

Full text of R-, H- and EUH-statements:

Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
H314	Causes severe skin burns and eye damage
H411	Toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Antigen (10060007)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Precautionary statements (CLP): P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

Other hazards not contributing to the classification:

This product contains inactivated dog/cat source material free of known diseases.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Thimerosal	(CAS No) 54-64-8 (EC no) 200-210-4 (EC index no) 080-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow breathing of fresh air. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.
Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct sunlight.

Storage temperature: 2 - 8 °C

Heat and ignition sources: Conditions to be avoided.

Prohibitions on mixed storage: Heat sources. Direct sunlight.

Special rules on packaging: Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

sodium azide (26628-22-8)		
EU	Local name	Sodium azide
EU	IOELV TWA (mg/m ³)	0,1 mg/m ³
EU	IOELV STEL (mg/m ³)	0,3 mg/m ³
EU	Notes	Skin
France	Local name	Azide de sodium
France	VME (mg/m ³)	0,1 mg/m ³
France	VLE (mg/m ³)	0,3 mg/m ³
Germany	Local name	Natriumazid
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,2 mg/m ³
Germany	Remark (TRGS 900)	DFG,EU
Italy	Local name	Azoturo di sodio
Italy	OEL TWA (mg/m ³)	0,1 mg/m ³
Italy	OEL STEL (mg/m ³)	0,3 mg/m ³
Portugal	Local name	Azida de sódio como Azida de sódio como vapor de Ácido hidroazóico
Portugal	OEL - Ceilings (mg/m ³)	0,29 mg/m ³
Portugal	OEL - Ceilings (ppm)	0,11 ppm

8.2 Exposure controls

Personal protective equipment: Avoid all unnecessary exposure.
 Materials for protective clothing: Wear suitable protective clothing
 Hand protection: Wear protective gloves
 Eye protection: Chemical goggles or safety glasses
 Respiratory protection: Respiratory protection equipment not absolutely necessary



Environmental exposure controls: Avoid release to the environment.
 Other information: Do not eat, drink or smoke during use.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified

Sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rat	50 mg/kg
LD50 dermal rabbit	20 mg/kg
Thimerosal (54-64-8)	
LD50 oral rat	75 mg/kg
LD50 dermal	98 mg/kg

Skin corrosion/irritation: Not classified; based on available data, the classification criteria are not met.

Serious eye damage/irritation: Not classified; based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Not classified; based on available data, the classification criteria are not met.

Germ cell mutagenicity: Not classified; based on available data, the classification criteria are not met.

Carcinogenicity: Not classified; based on available data, the classification criteria are not met.

Reproductive toxicity: Not classified; based on available data, the classification criteria are not met.

Specific target organ toxicity (single exposure): Not classified; based on available data, the classification criteria are not met.

Specific target organ toxicity (repeated exposure): Not classified; based on available data, the classification criteria are not met.

Aspiration hazard: Not classified; based on available data, the classification criteria are not met.

Potential adverse human health effects and symptoms: Not classified; based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2 mg/L (96 h)
Thimerosal (54-64-8)	
LC50 fish 1	21 mg/L (48 h) <i>Lepomis macrochirus</i>
LC50 fish 2	64,5 mg/L (48 h) <i>Oncorhynchus mykiss</i>

12.2 Persistence and degradability

Antigen: Not established.
Thimerosal (54-64-8): May cause long-term adverse effects in the environment.

12.3 Bioaccumulative potential

Not established.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII
This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

Denmark

Recommendations Danish Regulation: Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Inhalation)	Acute toxicity (inhal.), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects



SAFETY DATA SHEET
according to Regulation (EU) No. 2015/830

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Trade name: Antigen
Product number: Valid for ELISA products listed in the table on page 1

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 17: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

17.1 Product identifier

Trade name: Positive Control (10060004)
Product number: Valid for ELISA products listed in the table on page 1

17.2 Relevant identified uses of the substance or mixture and uses advised against

17.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

17.2.2 Uses advised against

No additional information available.

17.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

17.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 18: HAZARDS IDENTIFICATION

18.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

18.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Precautionary statements (CLP): P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing

18.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

Other hazards not contributing to the classification:

This product contains inactivated dog/cat source material free of known diseases.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 19: COMPOSITION/INFORMATION ON INGREDIENTS

19.1 Substances

Not applicable

19.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Thimerosal	(CAS No) 54-64-8 (EC no) 200-210-4 (EC index no) 080-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 20: FIRST AID MEASURES

20.1 Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow breathing of fresh air. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

20.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

20.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 21: FIREFIGHTING MEASURES

21.1 Extinguishing media

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media: Do not use a heavy water stream.

21.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

21.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 22: ACCIDENTAL RELEASE MEASURES

22.1 Personal precautions, protective equipment and emergency procedures

22.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

22.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.
Emergency procedures: Ventilate area.

22.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

22.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

22.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 23: HANDLING AND STORAGE

23.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

23.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products: Strong bases. Strong acids.
Incompatible materials: Sources of ignition. Direct sunlight.
Storage temperature: 2 - 8 °C
Heat and ignition sources: Conditions to be avoided.
Prohibitions on mixed storage: Heat sources. Direct sunlight.
Special rules on packaging: Keep only in original container.

23.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 24: EXPOSURE CONTROLS/PERSONAL PROTECTION

24.1 Control parameters

No additional information available.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

24.2 Exposure controls

Personal protective equipment:	Avoid all unnecessary exposure.
Materials for protective clothing:	Wear suitable protective clothing
Hand protection:	Wear protective gloves
Eye protection:	Chemical goggles or safety glasses
Respiratory protection:	Respiratory protection equipment not absolutely necessary



Environmental exposure controls:	Avoid release to the environment.
Other information:	Do not eat, drink or smoke during use.

SECTION 25: PHYSICAL AND CHEMICAL PROPERTIES

25.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	≈7.5
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

25.2 Other information

No additional information available.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 26: STABILITY AND REACTIVITY

26.1 Reactivity

Product is not explosive.

26.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

26.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

26.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

26.5 Incompatible materials

Strong acids. Strong bases.

26.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 27: TOXICOLOGICAL INFORMATION

27.1 Information on toxicological effects

Acute toxicity: Not classified

Thimerosal (54-64-8)	
LD50 oral rat	75 mg/kg
LD50 dermal	98 mg/kg

Skin corrosion/irritation:	Not classified; based on available data, the classification criteria are not met. pH: ≈ 7.5 (7 - 8)
Serious eye damage/irritation:	Not classified; based on available data, the classification criteria are not met. pH: ≈ 7.5 (7 - 8)
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not classified; based on available data, the classification criteria are not met.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 28: ECOLOGICAL INFORMATION

28.1 Toxicity

Thimerosal (54-64-8)	
LC50 fish 1	21 mg/L (48 h) <i>Lepomis macrochirus</i>
LC50 fish 2	64,5 mg/L (48 h) <i>Oncorhynchus mykiss</i>

28.2 Persistence and degradability

Positive Control: Not established.
Thimerosal (54-64-8): May cause long-term adverse effects in the environment.

28.3 Bioaccumulative potential

Not established.

28.4 Mobility in soil

No additional information available

28.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII
This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

28.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 29: DISPOSAL CONSIDERATIONS

29.1 Waste treatment methods

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials: Avoid release to the environment.

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 30: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
30.1 UN No.	Not regulated for transport			
30.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
30.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
30.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
30.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

30.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

30.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 31: REGULATORY INFORMATION

31.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

31.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

31.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

Trade name: Positive Control
Product number: Valid for ELISA products listed in the table on page 1

SZW-lijst van mutagene stoffen: None of the components are listed

Denmark

Recommendations Danish Regulation: Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

31.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 32: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Inhalation)	Acute toxicity (inhal.), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Negative Control (10060005)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Precautionary statements (CLP): P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

Other hazards not contributing to the classification:

This product contains inactivated dog/cat source material free of known diseases.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Thimerosal	(CAS No) 54-64-8 (EC no) 200-210-4 (EC index no) 080-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow breathing of fresh air. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.

Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct sunlight.

Storage temperature: 2 - 8 °C

Heat and ignition sources: Conditions to be avoided.

Prohibitions on mixed storage: Heat sources. Direct sunlight.

Special rules on packaging: Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Personal protective equipment:	Avoid all unnecessary exposure.
Materials for protective clothing:	Wear suitable protective clothing
Hand protection:	Wear protective gloves
Eye protection:	Chemical goggles or safety glasses
Respiratory protection:	Respiratory protection equipment not absolutely necessary



Environmental exposure controls:	Avoid release to the environment.
Other information:	Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified

Thimerosal (54-64-8)	
LD50 oral rat	75 mg/kg
LD50 dermal	98 mg/kg

Skin corrosion/irritation:	Not classified; based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Not classified; based on available data, the classification criteria are not met.
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not classified; based on available data, the classification criteria are not met.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 12: ECOLOGICAL INFORMATION**12.1 Toxicity**

Thimerosal (54-64-8)	
LC50 fish 1	21 mg/L (48 h) <i>Lepomis macrochirus</i>
LC50 fish 2	64,5 mg/L (48 h) <i>Oncorhynchus mykiss</i>

12.2 Persistence and degradability

Negative Control: Not established.

Thimerosal (54-64-8): May cause long-term adverse effects in the environment.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

Trade name: Negative Control
Product number: Valid for ELISA products listed in the table on page 1

SZW-lijst van mutagene stoffen: None of the components are listed
 NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:
 None of the components are listed
 NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:
 None of the components are listed
 NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:
 None of the components are listed

Denmark

Recommendations Danish Regulation: Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Inhalation)	Acute toxicity (inhal.), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Concentrated Wash Solution (0000004)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

Full text of H-statements: see section 16

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP):

- P272 - Contaminated work clothing should not be allowed out of the workplace
- P302+P352 - IF ON SKIN: Wash with plenty of water
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
- P362+P364 - Take off contaminated clothing and wash it before reuse
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
- P280 - Wear eye protection, protective gloves, protective clothing
- P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation:	Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Specific treatment (see ... on this label). Wash contaminated clothing before reuse.
First-aid measures after eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion:	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media:	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

Explosion hazard: Product is not explosive.
Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.
Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray.
Hygiene measures: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products: Strong bases. Strong acids.
Incompatible materials: Sources of ignition. Direct sunlight.
Storage temperature: 2 - 8 °C
Heat and ignition sources: Conditions to be avoided.
Prohibitions on mixed storage: Heat sources. Direct sunlight.
Special rules on packaging: Keep only in original container.

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Personal protective equipment:	Avoid all unnecessary exposure.
Materials for protective clothing:	Wear suitable protective clothing
Hand protection:	Wear protective gloves
Eye protection:	Chemical goggles or safety glasses
Respiratory protection:	Respiratory protection equipment not absolutely necessary



Environmental exposure controls:	Avoid release to the environment.
Other information:	Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	≈ 7.4 (7.1 - 7.7)
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rat	50 mg/kg
LD50 dermal rabbit	20 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2mg/L (96 h)

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

12.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

Trade name: Concentrated Wash Solution
Product number: Valid for ELISA products listed in the table on page 1

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 1, low hazard to water (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:

Chloracetamide is listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:

None of the components are listed

Denmark

Recommendations Danish Regulation: Young people below the age of 18 years are not allowed to use the product

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION*

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

* Changes made to previous version are marked with “ * ”.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Substrate A (0000001) / Substrate B (0000002)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922-55
D-24145 Kiel E-Mail: info@demeditec.de
Germany http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP): P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
EUH-statements: EUH210 - Safety data sheet available on request

2.3 Other hazards

Adverse physicochemical, human health and environmental effects:

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
3,3',5,5'-Tetramethylbenzidine	(CAS No) 54827-17-7 (EC no) 259-364-6	1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow breathing of fresh air. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.

Explosion hazard: Product is not explosive.

Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.

Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct sunlight.

Storage temperature: 2 - 8 °C

Heat and ignition sources: See: Conditions to be avoided.

Prohibitions on mixed storage: Heat sources. Direct sunlight.

Special rules on packaging: Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Personal protective equipment: Avoid all unnecessary exposure.

Materials for protective clothing: Wear suitable protective clothing

Hand protection: Wear protective gloves

Eye protection: Chemical goggles or safety glasses

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

Respiratory protection: Respiratory protection equipment not absolutely necessary



Environmental exposure controls: Avoid release to the environment.

Other information: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless to slightly yellow
Odour:	Odourless
Odour threshold:	No data available
pH:	3.35 - 3.75
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	168 °C
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Non flammable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Partly soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified
Skin corrosion/irritation:	Not classified; based on available data, the classification criteria are not met. pH: 3.35 - 3.75
Serious eye damage/irritation:	Not classified; based on available data, the classification criteria are not met. pH: 3.35 - 3.75
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not classified; based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No additional information available.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII
This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Additional information: Avoid release to the environment

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

- Overland transport: No data available
- Transport by sea: No data available
- Air transport: No data available
- Rail transport / Carriage prohibited (RID): No

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

Trade name: Substrate A, Substrate B
Product number: Valid for ELISA products listed in the table on page 1

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 2, hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:

None of the components are listed

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
EUH210	Safety data sheet available on request

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Stop Solution (0000003)
Product number: Valid for ELISA products listed in the table on page 1

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec.: For professional use only
Use of the substance/mixture: For In Vitro laboratory use

1.2.2 Uses advised against

No additional information available.

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH	Phone.: +49-(0)431 / 71922-0
Lise-Meitner-Str. 2	Fax: +49-(0)431 / 71922-55
D-24145 Kiel	E-Mail: info@demeditec.de
Germany	http://www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0
(Only available during the following office hours: 8:00 h – 16:30 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Corr. 1A	H314
Eye Dam. 1	H318

Full text of H-statements: see section 16

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]



Hazard pictograms (CLP):	
Signal word (CLP):	Danger
Hazardous ingredients:	Sulphuric acid
Hazard statements (CLP):	H314 - Causes severe skin burns and eye damage
Precautionary statements (CLP):	P260 - Do not breathe spray, gas, fume, dust, mist, vapours P264 - Wash hands thoroughly after handling P280 - Wear eye protection, protective gloves, protective clothing P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 - IF IN EYES: Rinse

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3 Other hazards

This mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sulphuric acid	(CAS No) 7664-93-9 (EC no) 231-639-5 (EC index no) 016-020-00-8	3 -5	Skin Corr. 1A

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures general:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after skin contact:	Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician
First-aid measures after eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after ingestion:	Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries:	Causes severe skin burns and eye damage.
Symptoms/injuries after eye contact:	Causes serious eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media:	Do not use a heavy water stream.

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Hazardous decomposition products in case of fire: Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip clean-up crew with proper protection.
Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4 Reference to other sections

See Section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact during pregnancy/while nursing.
Hygiene measures: Wash thoroughly after handling

7.2 Conditions for safe storage, including any incompatibilities

Technical measures: Comply with applicable regulations.
Storage conditions: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products: Strong bases. Strong acids.
Incompatible materials: Sources of ignition. Direct sunlight.
Storage temperature: 2 - 8 °C
Heat and ignition sources: Conditions to be avoided.

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

Prohibitions on mixed storage: Heat sources. Direct sunlight.
Special rules on packaging: Keep only in original container.

7.3 Specific end use(s)

This device is intended for In Vitro laboratory use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Sulphuric Acid (7664-93-9)	
European Union (IOELV)	Long-term value: 0.05 mg/m ³
Germany (AGS)	Long-term value: 0,1 mg/m ³ inhalable aerosol
Great Britain (WEL)	Long-term value: 0.05* mg/m ³ *mist: is defined as fraction

8.2 Exposure controls

Personal protective equipment: Avoid all unnecessary exposure.
Materials for protective clothing: Wear suitable protective clothing
Hand protection: Wear protective gloves
Eye protection: Chemical goggles or safety glasses
Respiratory protection: Respiratory protection equipment not absolutely necessary



Environmental exposure controls: Avoid release to the environment.
Other information: Do not eat, drink or smoke during use.

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	No data available
pH:	< 1.0
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	No data available
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Soluble in water
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Corrosive vapours. Product is not explosive.

10.2 Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2 °C - 8 °C.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Thermal decomposition generates : Corrosive vapours.

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified
Skin corrosion/irritation:	Causes severe skin burns and eye damage. pH: ≤ 1.0
Serious eye damage/irritation:	Causes serious eye damage. pH: ≤ 1.0
Respiratory or skin sensitisation:	Not classified; based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified; based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified; based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified; based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Not classified; based on available data, the classification criteria are not met.
Aspiration hazard:	Not classified; based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No additional information available

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6 Other adverse effects

Additional information: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

	ADR	IMDG	IATA	RID
14.1 UN No.	Not regulated for transport			
14.2 UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable
14.3 Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group	Not applicable	Not applicable	Not applicable	Not applicable
14.5 Environmental hazards	Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No No supplementary information available	Dangerous for the environment : No	Dangerous for the environment : No

14.6 Special precautions for user

No data available

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2 National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 1, low hazard to water (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act (Zwölfte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes (Störfall-Verordnung 12. BImSchV):

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-borstvoeding:

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-vruchtbaarheid:

Chloracetamide is listed

Trade name: Stop Solution
Product number: Valid for ELISA products listed in the table on page 1

NIET-limitatieve lijst van voor de voortplanting giftige stoffen-ontwikkeling:
None of the components are listed

Denmark

Recommendations Danish Regulation: Young people below the age of 18 years are not allowed to use the product

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information: None.

Full text of H- and EUH-statements:

Skin Corr. 1A	Skin corrosion/irritation, Category 1A
H314	Causes severe skin burns and eye damage.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product