SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
amended by EC Regulation N° 453/2010/EC

Version: 3.0
Revision date: 30.07.2015
Print date: 2016-02-12

Giardia lamblia ELISA

PRODUCT IDENTIFICATION

Product Name	Catalogue Number (REF)
Giardia lamblia ELISA	DE610001

Intended use: The Giardia lamblia ELISA is an In Vitro Diagnostic (IVD) immunoassay for the qualitative determination of Giardia specific antigens in human faecal specimens.

Company/Manufacturer identification:

Name: Demeditec Diagnostics GmbH
Address: Lise-Meitner-Str. 2
24145 Kiel
Germany
Contact: Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

COMPOSITION/INFORMATION ON INGREDIENTS

ELISA Kit Component	Composition
Coated Microtiter Strips	Plastic 96-well microtiter plate pre-coated with monoclonal antibodies to *Giardia lamblia* antigen.
Negative Control	Kit control sample, a *Giardia* negative formalinized stool supernatant.
Positive Control	Kit control sample, a diluted *Giardia* positive formalinized stool supernatant.
Specimen Diluent	A buffered solution with detergent and preservative to dilute patient samples.
Conjugate	Horseradish peroxidase(HRP)-conjugated specific monoclonal antibody to *Giardia* in a stabilized buffer solution with preservative.
Washing Buffer 20x	Concentrated buffered salt solution containing detergent and preservatives.
Chromogen Solution	Aqueous solution of TMB and hydrogen peroxide.
Stop Solution	Aqueous solution of 5 % phosphoric acid.

HAZARD INFORMATION

The components of the Demeditec Giardia lamblia ELISA kit are not classified as hazardous mixtures according to EC Regulation 1272/2008/EC.
They contain no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The kit components are in small sizes/volumes with a concentration below the acceptable limit for hazardous ingredients.
The usual precautionary measures are to be adhered to when handling chemicals.
Consult the included Safety Data Sheets of the individual components of the Assay for additional hazard and safety information.

No toxicological experiments have been performed on the product/kit and its different components. Quantitative data on the toxicity or the ecological effects of the individual mixtures in the kit are not available
When used and handled according to specifications, the product does not have any harmful effects to our knowledge. Use the product according to GLP and avoid dispersion into the environment to minimize the ecological risk.

Summary Hazard Information:

ELISA Kit Component	Safety Information
Coated Microtiter Strips	Contains no hazardous ingredients.
Negative and Positive Controls	See included SDS.
Specimen Diluent	See included SDS.
Conjugate	See included SDS.
Washing Buffer 20 x	See included SDS.
Chromogen Solution	See included SDS.
Stop Solution	See included SDS.

SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
amended by EC Regulation N° 453/2010/EC

Print date: 2016-02-12

Giardia lamblia ELISA: NEGATIVE/POSITIVE CTLs

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : NEGATIVE/POSITIVE CONTROLS for Giardia lamblia ELISA (DE610001)

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

The NEGATIVE/POSITIVE CONTROLS are prepared human stool samples that are resp. negative and positive for the presence of *Giardia* antigens. They are to be used as reagents in the *in vitro* diagnostic determinations of human faecal specimens. They are intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

1.4. Emergency Telephone Number

Phone : +49 (0) 431 / 71922 0 (available during office hours)

SECTION 2 - HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

These components of the Demeditec Giardia lamblia ELISA kit are not classified as hazardous mixtures according to EC Regulation 1272/2008/EC.
They contain no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The usual precautionary measures are to be adhered to when handling chemicals.

2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation 1272/2008/EC (EU-GHS/CLP):

Pictogram	: Not applicable.
Signal word	: Not applicable.
Hazard Statement(s)	: Not applicable.
Precautionary Statement(s)	: Not applicable.
Supplemental Hazard Statement(s)	: EUH210: Safety Data Sheet available on request.

2.3. Other hazards

- Some ingredients of the NEGATIVE/POSITIVE CTLs mixtures are derived from materials of biological origin. No known tests can guarantee that such materials are completely free from infectious agents. Caution should be exercised while handling the product: treat as potentially infectious.
- These products contain formalinized specimens. Formaldehyde may be toxic and is suspected of causing cancer.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
Not applicable.

3.2. Mixtures
The following substances used in the NEGATIVE/POSITIVE CTLs are considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

Hazardous Ingredient	REACH Registration N°	EC N°	CAS N°	Classification + H- and P-Statements	Concen-tration
Kit Component: NEGATIVE/POSITIVE CTLs					
Formaldehyde 	01-2119513723-45-xxxx	200-001-8	50-00-0	Acute Tox. 3 – H301 Acute Tox. 3 – H311 Acute Tox. 3 – H331 Skin Corr. 1B – H314 Skin Sens. 1 – H317 Carc. 1B – H350 Muta. 2 – H341 P201, P260, P280, P301+P310+P330, P303+P361+P353, P304+P340+P310, P305+P351+P338, P308+P311	<4 % (v/v)

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures
In general, it is advised to consult a physician and showing this safety data sheet to the doctor.
Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

4.2. Most important symptoms and effects, both acute and delayed
No data available.

4.3. Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5 - FIRE-FIGHTING MEASURES

5.1. Suitable fire-extinguishing media
All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards
These products are aqueous liquids and not likely to combust. Large quantities of these products, especially mixtures with formaline may generate hazardous carbon oxides.

5.3. Advice for fire-fighters
If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections

See section 13 for disposal considerations.

SECTION 7 - HANDLING AND STORAGE

7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the Demeditec Giardia lamblia ELISA kit.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters

NEGATIVE/POSITIVE CTLs do not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

Substance: Formaldehyde CAS N°. 50-00-0			Listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
Australia	1,2 mg/m^3	2,5 mg/m^3	
Austria	0,6 mg/m^3	0,6 mg/m^3	
Belgium	/	0,38 mg/m^3	
Denmark	0,4 mg/m^3	0,4 mg/m^3	
Finland	0,37 mg/m^3	1,2 mg/m^3	
France	0,5 ppm	1 ppm	
Germany	0,37 mg/m^3	0,74 mg/m^3	
Hungary	0,6 mg/m^3	0,6 mg/m^3	
Ireland	2,5 mg/m^3	2,5 mg/m^3	
Japan	0,1 ppm	/	
Latvia	0,5 mg/m^3	/	
New Zealand	0,33 ppm	1 ppm	
China	/	0,5 mg/m^3	
Poland	0,5 mg/m^3	1,0 mg/m^3	
South Korea	0,75 mg/m^3	1,5 mg/m^3	
Spain	/	0,37 mg/m^3	
Sweden	0.37 mg/m^3	0,74 mg/m^3	
Switzerland	0,37 mg/m^3	0,74 mg/m^3	
The Netherlands	0,15 mg/m^3	0,5 mg/m^3	
USA	0,75 ppm	2 ppm	
United Kingdom	2,5 mg/m^3	2,5 mg/m^3	

Other exposure limits

DNEL (Derived no effect level)					
Substance	**Parameter**	**Exposure**	**Value**	**Population**	**Effects**
Formaldehyde	DNEL	Long term, Inhalation	0,5 mg/m^3	Workers	Local
Formaldehyde	DNEL	Long term, inhalation	9 mg/m^3	Workers	Systemic

PNEC (Predicted No Effect Concentration) : No data available.

8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Hygiene measures: Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

Eye/face protection: Wear safety glasses with side-shields or goggles conforming to EN 166.

Skin protection: Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

Respiratory protection: Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN13487).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical appearance:	NEGATIVE/POSITIVE CTLs are clear colourless liquids.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	No data available.
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid,gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	The ingredient Formaldehyde may react with oxidizing agents.
Oxidizing properties:	Not fire-propagating.

9.2. Other information

No further information available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity
No test data related to reactivity available for this product.

10.2. Chemical stability
Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

10.5. Incompatible materials
Avoid contact with strong oxidizing agents.

10.6. Hazardous decomposition products
Thermal decomposition may produce small quantities of oxides of carbon.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

There are no toxicological data available for the NEGATIVE/POSITIVE CTLs as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Formaldehyde**:

Acute toxicity:

Acute toxicity data for Formaldehyde	
LD_{50},oral, rat	100,0 mg/kg
LD_{50},skin, rabbit	292,0 mg/kg

Corrosion/Irritation:

Eye contact: Causes eye irritation.
Ingestion: Toxic if swallowed.
Inhalation: Toxic if inhaled. Causes irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness. Possible absorption of through skin, causing systemic toxicity.

Sensitisation: May cause allergic skin reactions.

Germ cell mutagenicity: No data available on humans.

Carcinogenicity: Formaldehyde is listed as carcinogenic by IARC (group 1).

Mutagenicity: Formaldehyde is mutagenic in vitro for bacteria and mammalian cells, no data available on humans.

Reproductive toxigenicity: No data available on humans.

Specific target organ toxicity:
– **single exposure** No data available.

Specific target organ toxicity:
– **repeated exposure** No data available.

Aspiration hazard: No information available.

11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of NEGATIVE/POSITIVE CTLs as mixtures are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for ingredients used in the formulation of the NEGATIVE/POSITIVE CTLs:

Eco-toxicity data for Formaldehyde		
Fish Toxicity:	LC_{50} Fish	1,41- 330,0 mg/L/96 hr
Invertebrate Toxicity:	LC_{50} Crustaceans	954 - 1160 mg/L/48 hr
Invertebrate Toxicity:	EC_{50} Crustaceans	5,8 – 29,0 mg/L/48 hr

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

Formaldehyde is not listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative) at concentrations of 0.1 % or higher.

12.6. Other adverse effects

Formaldehyde is toxic to aquatic organisms. It may cause adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters. Do not discharge products into sewers or waterways.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: 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

This Safety Data Sheet complies with the requirements of Regulation 1907/2006/EC, amended by Regulation 453/2010/EC.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with directives 1999/45/EC, 91/155/EEC as amended in directive 2001/58/EC and with Annex I of Directive 98/79/EC.

Other EU Regulations:

These products are not ozone depleting agents and not persistent organic pollutants.

15.2. Chemical safety assessment

No data available.

SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol	
	GHS05 – Danger/Warning - Corrosive
	GHS06 – Danger - Toxic
	GHS08 – Danger/Warning – Systemic health hazards

Hazard Statements	
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

Precautionary Statements	
P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310+P330	IF SWALLOWED: Immediately call a POISON CENTER/doctor/… Rinse mouth.
P303+P361+P353	IF ON SKIN: 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 cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	If exposed or concerned: Get medical advice/attention.

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.
LC_{50} : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
LD_{50} : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
EC_{50} : Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
OEL : Occupational Exposure Limit (European threshold limit value).
REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.
STOT RE : Specific Target Organ Toxicity – Repeated Exposure.
TWA : Time Weighted Average 8 hours day.

Further information

The REACH registration number in section 3 is only available if the substance is registered by the REACH Agency. No registration number means that the substance or its use is exempted from registration according to article 2 of REACH Regulation 1907/2005/EC, or that the annual tonnage does not require a registration, or that registration is envisaged for a later deadline.

Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
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Print date: 2016-02-12

Giardia lamblia ELISA: Specimen Diluent

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : SPECIMEN DILUENT for Giardia lamblia ELISA (DE610001)

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

SPECIMEN DILUENT is an aqueous buffered solution containing detergent and preservatives. It is to be used as a reagent for dilution of patient samples during assay performance. It is intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

1.4. Emergency Telephone Number

Phone : +49 (0) 431 / 71922 0 (available during office hours)

SECTION 2 - HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This component of the Demeditec Giardia lamblia ELISA kit is not classified as a hazardous mixture according to EC Regulation 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The usual precautionary measures are to be adhered to when handling chemicals

2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation 1272/2008/EC (EU-GHS/CLP):

Pictogram	: Not applicable.
Signal word	: Not applicable.
Hazard Statement(s)	: Not applicable.
Precautionary Statement(s)	: Not applicable.
Supplemental Hazard Statement(s)	: EUH210: Safety Data Sheet available on request.

2.3. Other hazards

SPECIMEN DILUENT contains Thimerosal as a preservative. Thimerosal is very toxic and possible fatal if swallowed, in contact with skin or when inhaled. It may cause damage to organs through prolonged or repeated exposure.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
Not applicable.

3.2. Mixtures
The following substance used in SPECIMEN DILUENT is considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

Hazardous Ingredient	REACH Registration N°	EC N°	CAS N°	Classification + H- and P-Statements	Concen-tration
Kit Component: SPECIMEN DILUENT					
Thimerosal 	Not listed	200-210-4	54-64-8	Acute Tox. 2 – H330 Acute Tox. 1 – H310 Acute Tox. 2 – H300 Aquatic Acute 1 – H410 Aquatic Chronic 1 – H410 STOT RE 2 – H373 P260, P264 P273, P280, P284, P302+P352	0.5 % (w/v)

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures
In general, it is advised to consult a physician and showing this safety data sheet to the doctor.
Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

4.2. Most important symptoms and effects, both acute and delayed
No data available.

4.3. Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5 - FIRE-FIGHTING MEASURES

5.1. Suitable fire-extinguishing media
All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards
Large quantities of this product may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes, e.g. nitric oxides. Thermal decomposition of Thimerosal may lead to generation of carbon oxides, sulphur oxides, sodium oxides, mercury and mercury oxides

5.3. Advice for fire-fighters
If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections

See section 13 for disposal considerations.

SECTION 7 - HANDLING AND STORAGE

7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the Demeditec Giardia lamblia ELISA kit.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters

SPECIMEN DILUENT does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

Substance: Thimerosal CAS N°. 54-64-8			Not listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
n/a	n/a	n/a	

Other exposure limits
DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Hygiene measures: Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

Eye/face protection: Wear safety glasses with side-shields or goggles conforming to EN 166.

Skin protection: Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

Respiratory protection: Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN13487).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical appearance:	SPECIMEN DILUENT is a clear, colourless liquid.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	No information.
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid,gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

9.2. Other information

No further information available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity
No test data related to reactivity available for this product.

10.2. Chemical stability
Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods. Store away from areas of high fire hazard.

10.5. Incompatible materials
Avoid contact with strong oxidizing agents.

10.6. Hazardous decomposition products
Hazardous thermal decomposition products in small quantities, i.e. nitric oxide vapours are possible in a fire. Thermal decomposition of Thimerosal may lead to generation of carbon oxides, sulphur oxides, sodium oxides, mercury and mercury oxides.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
There are no toxicological data available for SPECIMEN DILUENT as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Thimerosal**

Acute toxicity:

Acute toxicity data for Thimerosal	
LD_{50},oral, rat	75,0 mg/kg
LD_{50},subcutaneous, rat	98,0 mg/kg

Corrosion/Irritation:

Eye contact: Causes mild eye irritation.
Ingestion: May be fatal if swallowed.
Inhalation: May be fatal if inhaled. Possible irritation of respiratory tract.
Skin contact: May cause skin irritation or redness. May be fatal if absorbed through skin.

Sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Germ cell mutagenicity: No data available on humans.
Genotoxicity in vitro - hamster - lungs
Genotoxicity in vivo - mouse - intraperitoneal

Carcinogenicity: Thimerosal is not confirmed as carcinogenic by IARC at a concentration of < 0,1 % (w/v).

Mutagenicity: No data available on humans.

Reproductive toxigenicity: No data available on humans.

Specific target organ toxicity: No data available.
– **single exposure**

Specific target organ toxicity: May cause damage through prolonged exposure
repeated exposure (affected organs not specified).

Aspiration hazard: No data available.

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2. Additional toxicological information
Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of SPECIMEN DILUENT as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of SPECIMEN DILUENT:

Eco-toxicity data for Thimerosal		
Fish Toxicity:	LC_{50} Rainbow trout	21,2 mg/L/48 hr

12.2. Persistence and degradability

Not readily biodegradable.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

Substance meets the criteria for PBT or vPvB according to Regulation EC 1907/2006, Annex XIII.

12.6. Other adverse effects

Thimerosal is very toxic to aquatic organisms. It may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters.
Do not discharge products into sewers or waterways.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations. Observe all Federal, Regional and Local legislation concerning health and pollution. Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: 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

This Safety Data Sheet complies with the requirements of Regulation 1907/2006/EC, amended by Regulation 453/2010/EC.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with directives 1999/45/EC, 91/155/EEC as amended in directive 2001/58/EC and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not an ozone depleting agent and not a persistent organic pollutant.

15.2. Chemical safety assessment

No data available.

SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol	
	GHS06 – Danger – Toxic
	GHS08 – Danger/Warning – Systemic health effects
	GHS09 – Warning - Environment

Hazard Statements	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary Statements	
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash hands throroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P284	In case of inadequate ventilation, wear respiratory protection.
P302+P352	IF ON SKIN: Wash with plenty of water.

Abbreviations used in the text

ACGIH	:	American Conference of Governmental Industrial Hygienists.
ADR	:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS	:	Chemical Abstracts Service.
CLP	:	Classification, Labelling, Packaging.
GHS	:	Globally Harmonized System of Classification and Labelling of Chemicals.
IARC	:	International Agency for Research on Cancer.
IATA	:	International Air Transport Association.
IATA-DGR	:	Dangerous Goods Regulation by IATA.
ICAO	:	International Civil Aviation Organization.
IMDG	:	International Maritime Code for Dangerous Goods.
K_{ow}	:	Octanol-Water Partition Coefficient.
LC_{50}	:	Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
OEL	:	Occupational Exposure Limit (European threshold limit value).
REACH	:	Registration, Evaluation, Authorization and Restriction of Chemicals.
RID	:	Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL	:	Short Term Exposure Limit.
STOT RE	:	Specific Target Organ Toxicity – Repeated Exposure.
TWA	:	Time Weighted Average 8 hours day.

Further information:
The REACH registration number in section 3 is only available if the substance is registered by the REACH Agency. No registration number means that the substance or its use is exempted from registration according to article 2 of REACH Regulation 1907/2005/EC, or that the annual tonnage does not require a registration, or that registration is envisaged for a later deadline.

Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.

The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
amended by EC Regulation N° 453/2010/EC

Print date: 2016-02-12

Giardia lamblia ELISA: Conjugate

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : CONJUGATE for Giardia lamblia ELISA
(DE610001)

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

CONJUGATE is a Horseradish peroxidase(HRP)-conjugated specific monoclonal antibody to *Giardia* antigen, prepared in a stabilized buffer solution with preservatives. It is to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

1.4. Emergency Telephone Number

Phone : +49 (0) 431 / 71922 0 (available during office hours)

SECTION 2 - HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This component of the Demeditec Giardia lamblia ELISA kit is not classified as a hazardous mixture according to EC Regulation 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The usual precautionary measures are to be adhered to when handling chemicals

2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation 1272/2008/EC (EU-GHS/CLP):

Pictogram	: Not applicable.
Signal word	: Not applicable.
Hazard Statement(s)	: Not applicable.
Precautionary Statement(s)	: Not applicable.
Supplemental Hazard Statement(s)	: EUH210: Safety Data Sheet available on request.

2.3. Other hazards

CONJUGATE contains Thimerosal as a preservative. Thimerosal is very toxic and possible fatal if swallowed, in contact with skin or when inhaled. It may cause damage to organs through prolonged or repeated exposure.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
Not applicable.

3.2. Mixtures
The following substance used in CONJUGATE is considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

Hazardous Ingredient	REACH Registration N°	EC N°	CAS N°	Classification + H- and P-Statements	Concen-tration
Kit Component: CONJUGATE					
Thimerosal 	Not listed	200-210-4	54-64-8	Acute Tox. 2 – H330 Acute Tox. 1 – H310 Acute Tox. 2 – H300 Aquatic Acute 1 – H410 Aquatic Chronic 1 – H410 STOT RE 2 – H373 P260, P264 P273, P280, P284, P302+P352	0.5 % (w/v)

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures
In general, it is advised to consult a physician and showing this safety data sheet to the doctor.
Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

4.2. Most important symptoms and effects, both acute and delayed
No data available.

4.3. Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5 - FIRE-FIGHTING MEASURES

5.1. Suitable fire-extinguishing media
All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards
Large quantities of this product may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes, e.g. nitric oxides. Thermal decomposition of Thimerosal may lead to generation of carbon oxides, sulphur oxides, sodium oxides, mercury and mercury oxides

5.3. Advice for fire-fighters
If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections

See section 13 for disposal considerations.

SECTION 7 - HANDLING AND STORAGE

7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the Demeditec Giardia lamblia ELISA kit.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters

CONJUGATE does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

Substance: Thimerosal CAS N°. 54-64-8			Not listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
n/a	n/a	n/a	

Other exposure limits

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Hygiene measures: Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

Eye/face protection: Wear safety glasses with side-shields or goggles conforming to EN 166.

Skin protection: Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.
Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

Respiratory protection: Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN13487).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical appearance:	CONJUGATE is a clear, slightly yellowish-coloured liquid.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	No information.
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid,gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

9.2. Other information

No further information available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity
No test data related to reactivity available for this product.

10.2. Chemical stability
Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods. Store away from areas of high fire hazard.

10.5. Incompatible materials
Avoid contact with strong oxidizing agents.

10.6. Hazardous decomposition products
Hazardous thermal decomposition products in small quantities, i.e. nitric oxide vapours are possible in a fire. Thermal decomposition of Thimerosal may lead to generation of carbon oxides, sulphur oxides, sodium oxides, mercury and mercury oxides.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
There are no toxicological data available for CONJUGATE as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Thimerosal**

Acute toxicity:

Acute toxicity data for Thimerosal	
LD_{50},oral, rat	75,0 mg/kg
LD_{50},subcutaneous, rat	98,0 mg/kg

Corrosion/Irritation:

Eye contact: Causes mild eye irritation.
Ingestion: May be fatal if swallowed.
Inhalation: May be fatal if inhaled. Possible irritation of respiratory tract.
Skin contact: May cause skin irritation or redness. May be fatal if absorbed through skin.

Sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Germ cell mutagenicity: No data available on humans.
Genotoxicity in vitro - hamster - lungs
Genotoxicity in vivo - mouse - intraperitoneal

Carcinogenicity: Thimerosal is not confirmed as carcinogenic by IARC at a concentration of < 0,1 % (w/v).

Mutagenicity: No data available on humans.

Reproductive toxigenicity: No data available on humans.

Specific target organ toxicity: No data available.
– **single exposure**

Specific target organ toxicity: May cause damage through prolonged exposure
– **repeated exposure** (affected organs not specified).

Aspiration hazard: No data available.

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2. Additional toxicological information
Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of CONJUGATE as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of CONJUGATE:

Eco-toxicity data for Thimerosal		
Fish Toxicity:	LC_{50} Rainbow trout	21,2 mg/L/48 hr

12.2. Persistence and degradability

Not readily biodegradable.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

5.4. Results of PBT and vPvB assessment

Substance meets the criteria for PBT or vPvB according to Regulation EC 1907/2006, Annex XIII.

5.5. Other adverse effects

Thimerosal is very toxic to aquatic organisms. It may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters.
Do not discharge products into sewers or waterways.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.
Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: 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

This Safety Data Sheet complies with the requirements of Regulation 1907/2006/EC, amended by Regulation 453/2010/EC.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with directives 1999/45/EC, 91/155/EEC as amended in directive 2001/58/EC and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not an ozone depleting agent and not a persistent organic pollutant.

15.2. Chemical safety assessment

No data available.

SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol	
	GHS06 – Danger – Toxic
	GHS08 – Danger/Warning – Systemic health effects
	GHS09 – Warning - Environment

Hazard Statements	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary Statements	
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash hands throroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P284	In case of inadequate ventilation, wear respiratory protection.
P302+P352	IF ON SKIN: Wash with plenty of water.

Abbreviations used in the text

ACGIH	:	American Conference of Governmental Industrial Hygienists.
ADR	:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS	:	Chemical Abstracts Service.
CLP	:	Classification, Labelling, Packaging.
GHS	:	Globally Harmonized System of Classification and Labelling of Chemicals.
IARC	:	International Agency for Research on Cancer.
IATA	:	International Air Transport Association.
IATA-DGR	:	Dangerous Goods Regulation by IATA.
ICAO	:	International Civil Aviation Organization.
IMDG	:	International Maritime Code for Dangerous Goods.
K_{ow}	:	Octanol-Water Partition Coefficient.
LC_{50}	:	Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
OEL	:	Occupational Exposure Limit (European threshold limit value).
REACH	:	Registration, Evaluation, Authorization and Restriction of Chemicals.
RID	:	Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL	:	Short Term Exposure Limit.
STOT RE	:	Specific Target Organ Toxicity – Repeated Exposure.
TWA	:	Time Weighted Average 8 hours day.

Further information:

The REACH registration number in section 3 is only available if the substance is registered by the REACH Agency. No registration number means that the substance or its use is exempted from registration according to article 2 of REACH Regulation 1907/2005/EC, or that the annual tonnage does not require a registration, or that registration is envisaged for a later deadline.

Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
amended by EC Regulation N° 453/2010/EC

Print date: 2016-02-12

Giardia lamblia ELISA: Washing Buffer 20x

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : WASHING BUFFER 20x for Giardia lamblia ELISA (DE610001)

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

WASHING BUFFER 20x is a concentrated buffered salt solution containing detergent and preservatives to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

1.4. Emergency Telephone Number

Phone : +49 (0) 431 / 71922 0 (available during office hours)

SECTION 2 - HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This component of the Demeditec Giardia lamblia ELISA kit is not classified as a hazardous mixture according to EC Regulation 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The usual precautionary measures are to be adhered to when handling chemicals

2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation 1272/2008/EC (EU-GHS/CLP):

Pictogram	: Not applicable.
Signal word	: Not applicable.
Hazard Statement(s)	: Not applicable.
Precautionary Statement(s)	: Not applicable.
Supplemental Hazard Statement(s)	: EUH210: Safety Data Sheet available on request.

2.3. Other hazards

WASHING BUFFER 20x contains Thimerosal as a preservative. Thimerosal is very toxic and possible fatal if swallowed, in contact with skin or when inhaled. It may cause damage to organs through prolonged or repeated exposure.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
Not applicable.

3.2. Mixtures
The following substance used in WASHING BUFFER 20x is considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

Hazardous Ingredient	REACH Registration N°	EC N°	CAS N°	Classification + H- and P-Statements	Concen-tration
Kit Component: WASHING BUFFER 20x					
Thimerosal 	Not listed	200-210-4	54-64-8	Acute Tox. 2 – H330 Acute Tox. 1 – H310 Acute Tox. 2 – H300 Aquatic Acute 1 – H410 Aquatic Chronic 1 – H410 STOT RE 2 – H373 P260, P264 P273, P280, P284, P302+P352	0.5 % (w/v)

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures
In general, it is advised to consult a physician and showing this safety data sheet to the doctor.
Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

4.2. Most important symptoms and effects, both acute and delayed
No data available.

4.3. Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5 - FIRE-FIGHTING MEASURES

5.1. Suitable fire-extinguishing media
All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards
Large quantities of this product may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes, e.g. nitric oxides. Thermal decomposition of Thimerosal may lead to generation of carbon oxides, sulphur oxides, sodium oxides, mercury and mercury oxides

6.5. Advice for fire-fighters
If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections

See section 13 for disposal considerations.

SECTION 7 - HANDLING AND STORAGE

7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the Demeditec Giardia lamblia ELISA kit.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters

WASHING BUFFER 20x does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

Substance: Thimerosal CAS N°. 54-64-8			Not listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
n/a	n/a	n/a	

Other exposure limits

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Hygiene measures: Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

Eye/face protection: Wear safety glasses with side-shields or goggles conforming to EN 166.

Skin protection: Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

Respiratory protection: Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN13487).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical appearance:	WASHING BUFFER 20x is a clear, colourless liquid.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	No information.
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid,gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

9.2. Other information

No further information available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity
No test data related to reactivity available for this product.

10.2. Chemical stability
Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods. Store away from areas of high fire hazard.

10.5. Incompatible materials
Avoid contact with strong oxidizing agents.

10.6. Hazardous decomposition products
Hazardous thermal decomposition products in small quantities, i.e. nitric oxide vapours are possible in a fire. Thermal decomposition of Thimerosal may lead to generation of carbon oxides, sulphur oxides, sodium oxides, mercury and mercury oxides.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
There are no toxicological data available for WASHING BUFFER 20x as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Thimerosal**

Acute toxicity:

Acute toxicity data for Thimerosal	
LD_{50},oral, rat	75,0 mg/kg
LD_{50},subcutaneous, rat	98,0 mg/kg

Corrosion/Irritation:
Eye contact: Causes mild eye irritation.
Ingestion: May be fatal if swallowed.
Inhalation: May be fatal if inhaled. Possible irritation of respiratory tract.
Skin contact: May cause skin irritation or redness. May be fatal if absorbed through skin.

Sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Germ cell mutagenicity: No data available on humans.
Genotoxicity in vitro - hamster - lungs
Genotoxicity in vivo - mouse - intraperitoneal

Carcinogenicity: Thimerosal is not confirmed as carcinogenic by IARC at a concentration of < 0,1 % (w/v).

Mutagenicity: No data available on humans.

Reproductive toxigenicity: No data available on humans.

Specific target organ toxicity: No data available.
– **single exposure**

Specific target organ toxicity: May cause damage through prolonged exposure
repeated exposure (affected organs not specified).

Aspiration hazard: No data available.

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2. Additional toxicological information
Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of WASHING BUFFER 20x as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for preservatives used in the formulation of WASHING BUFFER 20x:

Eco-toxicity data for Thimerosal		
Fish Toxicity:	LC_{50} Rainbow trout	21,2 mg/L/48 hr

12.2. Persistence and degradability

Not readily biodegradable.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

1.5. Results of PBT and vPvB assessment

Substance meets the criteria for PBT or vPvB according to Regulation EC 1907/2006, Annex XIII.

1.6. Other adverse effects

Thimerosal is very toxic to aquatic organisms. It may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters.
Do not discharge products into sewers or waterways.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.
Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID: No limitations
Maritime transport (sea) IMDG: No limitations
Air transport (air) ICAO/IATA: No limitations

14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: 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

This Safety Data Sheet complies with the requirements of Regulation 1907/2006/EC, amended by Regulation 453/2010/EC.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with directives 1999/45/EC, 91/155/EEC as amended in directive 2001/58/EC and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not an ozone depleting agent and not a persistent organic pollutant.

15.2. Chemical safety assessment

No data available.

SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol	
	GHS06 – Danger – Toxic
	GHS08 – Danger/Warning – Systemic health effects
	GHS09 – Warning - Environment

Hazard Statements	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary Statements	
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash hands throroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P284	In case of inadequate ventilation, wear respiratory protection.
P302+P352	IF ON SKIN: Wash with plenty of water.

Abbreviations used in the text

ACGIH	:	American Conference of Governmental Industrial Hygienists.
ADR	:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS	:	Chemical Abstracts Service.
CLP	:	Classification, Labelling, Packaging.
GHS	:	Globally Harmonized System of Classification and Labelling of Chemicals.
IARC	:	International Agency for Research on Cancer.
IATA	:	International Air Transport Association.
IATA-DGR	:	Dangerous Goods Regulation by IATA.
ICAO	:	International Civil Aviation Organization.
IMDG	:	International Maritime Code for Dangerous Goods.
K_{ow}	:	Octanol-Water Partition Coefficient.
LC_{50}	:	Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
OEL	:	Occupational Exposure Limit (European threshold limit value).
REACH	:	Registration, Evaluation, Authorization and Restriction of Chemicals.
RID	:	Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL	:	Short Term Exposure Limit.
STOT RE	:	Specific Target Organ Toxicity – Repeated Exposure.
TWA	:	Time Weighted Average 8 hours day.

Further information:

The REACH registration number in section 3 is only available if the substance is registered by the REACH Agency. No registration number means that the substance or its use is exempted from registration according to article 2 of REACH Regulation 1907/2005/EC, or that the annual tonnage does not require a registration, or that registration is envisaged for a later deadline.

Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.
The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
amended by EC Regulation N° 453/2010/EC

Print date: 2016-02-12

Giardia lamblia ELISA: CHROMOGEN SOLUTION

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : CHROMOGEN SOLUTION for Giardia lamblia ELISA (DE610001)

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

CHROMOGEN SOLUTION is a colorimetric substrate solution, based on the marker enzyme Horse Radish Peroxidase, to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

1.4. Emergency Telephone Number

Phone : +49 (0) 431 / 71922 0 (available during office hours)

SECTION 2 - HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This component of the Demeditec Giardia lamblia ELISA kit is not classified as a hazardous mixture according to EC Regulation 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The usual precautionary measures are to be adhered to when handling chemicals.

2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation 1272/2008/EC (EU-GHS/CLP)

Pictogram	: Not applicable.
Signal word	: Not applicable.
Hazard Statement(s)	: Not applicable.
Precautionary Statement(s)	: Not applicable.
Supplemental Hazard Statement(s)	: EUH210: Safety Data Sheet available on request.

2.3. Other hazards

None of the components of this product are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable.

3.2. Mixtures

The following substances used in the CHROMOGEN SOLUTION are considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

Hazardous Ingredient	REACH Registration N°	EC N°	CAS N°	Classification + H- and P-Statements	Concen-tration
Kit Component: CHROMOGEN SOLUTION					
TMB (3,3',5,5'-Tetramethylbenzidin) 	Not Listed	259-364-6	54827-17-7	Skin Irrit. 2 – H315 Eye Irrit. 2 – H319 STOT SE 3 – H335 P261, P305+P351+P338	< 0,1 % (w/v)
Hydrogen peroxide 	01-211948545-22-xxxx	231-765-0	7722-84-1	Acute Tox. 4 – H302 Eye Dam. 1 – H318 P280 , P305+P351+P338	< 0.1 % (w/v)

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.
Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 - FIRE-FIGHTING MEASURES

5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards

This product is an aqueous liquid and not likely to combust. Large quantities of these products may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes, e.g. nitric oxides.

5.3. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections

See section 13 for disposal considerations.

SECTION 7 - HANDLING AND STORAGE

7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the Demeditec Giardia lamblia ELISA kit.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters

CHROMOGEN SOLUTION does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

Substance: 3,3',5,5'-Tetramethylbenzidin (TMB) CAS N°. 54827-17-7			Not listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
n/a	n/a	n/a	

Substance: Hydrogen peroxide CAS N°. 7722-84-1			Listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
Australia	1,4 mg/m^3	/	
Austria	1,4 mg/m^3	2,8 mg/m^3	
Belgium	1,4 mg/m^3	/	
Canada	1,4 mg/m^3	/	
Denmark	1,4 mg/m^3	2,8 mg/m^3	
Finland	1,4 mg/m^3	4,2 mg/m^3	
France	1,5 mg/m^3	/	
Germany	0,71 mg/m^3	0,71 mg/m^3	
Ireland	1,5 mg/m^3	3,0 mg/m^3	
China	1,5 mg/m^3	/	
Singapore	1,4 mg/m^3	/	
South Korea	1,5 mg/m^3	/	
Spain	1,4 mg/m^3	/	
Sweden	1,4 mg/m^3	3,0 mg/m^3	
Switzerland	0,71 mg/m^3	0,71 mg/m^3	
USA	1,4 mg/m^3	/	
United Kingdom	1,4 mg/m^3	2,8 mg/m^3	

Other exposure limits

DNEL (Derived no effect level)					
Substance	**Parameter**	**Exposure**	**Value**	**Population**	**Effects**
TMB	DNEL	no data	no data	no data	no data
Hydrogen peroxide	DNEL	Long term, inhalation	1,4 mg/m^3	Workers	Local effects

PNEC (Predicted No Effect Concentration) : No data available.

8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Hygiene measures:	Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.
Eye/face protection:	Wear safety glasses with side-shields or goggles conforming to EN 166.
Skin protection:	Hand protection: Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374. Mean Breakthrough Time > 480 min. Body protection: Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved. Change contaminated clothing immediately.
Respiratory protection:	Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system. If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN13487).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical appearance:	CHROMOGEN SOLUTION is a colourless to slightly bluish-coloured liquid.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	3,6 – 4,2
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid,gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	No data available.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

9.2. Other information

No further information available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity
No test data related to reactivity available for this product.

10.2. Chemical stability
Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

10.5. Incompatible materials
Avoid contact with strong oxidizing agents, metals and metal salts: possible destruction of the quality of the product.

10.6. Hazardous decomposition products
Hazardous thermal decomposition products in small quantities, i.e. nitric oxide vapours are possible in a fire.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
There are no toxicological data available for the CHROMOGEN SOLUTION as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **TMB**:

Acute toxicity:

Acute toxicity data for TMB
no data available

Corrosion/Irritation:
Eye contact: Causes serious eye irritation.
Ingestion: Harmful if swallowed.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness.

Germ cell mutagenicity: No data available on humans.
Genotoxicity in vitro - mouse - lymphocyte
Mutation in mammalian somatic cells.

Carcinogenicity: TMB is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH.

Mutagenicity: No data available on humans.

Reproductive toxigenicity: No data available on humans.

Specific target organ toxicity: No data available.
– **single exposure**

Specific target organ toxicity: No data available.
– **repeated exposure**

Aspiration hazard: No data available.

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Hydrogen peroxide**:

Acute toxicity:

Acute toxicity data for Hydrogen peroxide	
LD_{5O},skin, rabbit	3000,0 mg/kg
LD_{5O},oral, rabbit	376,0 mg/kg

Corrosion/Irritation:

Eye contact: Causes serious eye irritation. Conjunctivitis.
Ingestion: Irritation of mucous membranes in mouth, pharynx, oesophagus, gastrointestinal tract.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation after prolonged exposure. May cause skin burns.

Germ cell mutagenicity: No data available on humans.

Carcinogenicity: Hydrogen peroxide is not listed as carcinogenic.

Mutagenicity: No data available on humans.

Reproductive toxigenicity: No data available on humans.

Specific target organ toxicity – single exposure: Not classified as specific target organ toxicant.

Specific target organ toxicity – repeated exposure: Not classified as specific target organ toxicant.

Aspiration hazard: No data available.

Signs and symptoms of exposure:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2. Additional toxicological information

Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of CHROMOGEN SOLUTION as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for the components used in the formulation of the ChROMOGEN SOLUTION:

Eco-toxicity data for TMB
No data available

Eco-toxicity data for Hydrogen peroxide		
Fish Toxicity:	LC_{50} Fish	22,0 – 26,7 mg/L/96 hr
Invertebrate Toxicity:	EC_{50} Water flea	7,7 mg/L/24 hr
Algae Toxicity:	IC_{50} Fresh water algae	2,5 mg/L/72 hr

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Other adverse effects

No information available.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.

Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID:	No limitations
Maritime transport (sea) IMDG:	No limitations
Air transport (air) ICAO/IATA:	No limitations

14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: 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

This Safety Data Sheet complies with the requirements of Regulation 1907/2006/EC, amended by Regulation 453/2010/EC.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with directives 1999/45/EC, 91/155/EEC as amended in directive 2001/58/EC and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is not an ozone depleting agent and not a persistent organic pollutant.

15.2. Chemical safety assessment

No data available.

SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol	
	GHS05 – Danger/Warning - Corrosive
	GHS07 – Warning - Irritant

Hazard Statements	
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary Statements	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.
LC_{50} : Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
LD_{50} : Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
EC_{50} : Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
IC_{5O} : Inhibition concentration whereby 50 % of a sample of test organisms show an inhibition of a certain target activity following a specified exposure time.
OEL : Occupational Exposure Limit (European threshold limit value).
REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.
STOT RE : Specific Target Organ Toxicity – Repeated Exposure.
TWA : Time Weighted Average 8 hours day.

Further information

The REACH registration number in section 3 is only available if the substance is registered by the REACH Agency. No registration number means that the substance or its use is exempted from registration according to article 2 of REACH Regulation 1907/2005/EC, or that the annual tonnage does not require a registration, or that registration is envisaged for a later deadline.

Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution.

The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.

SAFETY DATA SHEET

Conforms to EC Regulation N° 1907/2006/EC,
amended by EC Regulation N° 453/2010/EC

Print date: 2016-02-12

Giardia lamblia ELISA: STOP SOLUTION

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : STOP SOLUTION for Giardia lamblia ELISA
(DE610001)

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

STOP SOLUTION is an aqueous phosphoric acid solution to be used as a reagent in the *in vitro* diagnostic determinations of human samples. It is intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Tel. +49 (0) 431 / 71922 0
Fax +49 (0) 431 / 71922 55
E-mail: info@demeditec.de
Web site: www.demeditec.de

1.4. Emergency Telephone Number

Phone : +49 (0) 431 / 71922 0 (available during office hours)

SECTION 2 - HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This component of the Demeditec Giardia lamblia ELISA kit is not classified as a hazardous mixture according to EC Regulation 1272/2008/EC.
It contains no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Directives 67/548/EEC or 1999/45/EC.
The usual precautionary measures are to be adhered to when handling chemicals.

2.2. Label elements

This product does not need to be labelled in accordance with EC Regulation 1272/2008/EC (EU-GHS/CLP)

Pictogram	: Not applicable.
Signal word	: Not applicable.
Hazard Statement(s)	: Not applicable.
Precautionary Statement(s)	: Not applicable.
Supplemental Hazard Statement(s)	: EUH210: Safety Data Sheet available on request.

2.3. Other hazards

None of the components of this product are listed as PBT (Persistent/Bio-accumulative/Toxic)or vPvB (very Persistent/very Bio-accumulative).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable.

3.2. Mixtures

The following substance used in the STOP SOLUTION is considered hazardous.
At the indicated applied concentrations, it does not warrant hazard labelling.

Hazardous Ingredient	REACH Registration N°	EC N°	CAS N°	Classification + H- and P-Statements	Concen-tration
Kit Component: STOP SOLUTION					
Phosphoric acid 	01-2119485924-24-xxxx	231-633-2	7664-38-2	Skin Corr. 1B – H314 Skin Irrit. 2 – H315 Eye Irrit. 2 – H319 P280 , P302+P352, P305+P351+P338	5 % (v/v)

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures

In general, it is advised to consult a physician and showing this safety data sheet to the doctor.

Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 - FIRE-FIGHTING MEASURES

5.1. Suitable fire-extinguishing media

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards

This product is an aqueous liquid and not likely to combust. Non-flammable. Hydrogen gas is released in contact with most metals. May generate phosphoric oxides in case of fire.

5.3. Advice for fire-fighters

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing – plastic gloves, eye protection and laboratory overall – to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections

See section 13 for disposal considerations.

SECTION 7 - HANDLING AND STORAGE

7.1. Handling instructions

Handle according to good industrial hygiene and safety practices for diagnostic products.
Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place.
Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions

Store tightly closed in original packaging within temperature limits indicated on the label.
Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s)

For in vitro diagnostic use only. Use only in accordance with the Instructions For Use supplied with the Demeditec Giardia lamblia ELISA kit.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters

STOP SOLUTION does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits

Substance: Phosphoric acid CAS N°. 7664-38-2			Listed
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**	
Australia	1,0 mg/m^3	/	
Austria	1,0 mg/m^3	2,0 mg/m^3	
Belgium	1,0 mg/m^3	2,0 mg/m^3	
Canada	1,0 mg/m^3	3,0 mg/m^3	
Denmark	1,0 mg/m^3	2,0 mg/m^3	
European Union	1,0 mg/m^3	2,0 mg/m^3	
Finland	1,0 mg/m^3	2,0 mg/m^3	
France	1,0 mg/m^3	2,0 mg/m^3	
Germany	2,0 mg/m^3	4,0 mg/m^3	(Inhalable aerosol)
Hungary	1,0 mg/m^3	2,0 mg/m^3	
Ireland	1,0 mg/m^3	2,0 mg/m^3	
Italy	1,0 mg/m^3	2,0 mg/m^3	
New zealand	1,0 mg/m^3	/	
China	1,0 mg/m^3	3,0 mg/m^3	
Poland	1,0 mg/m^3	2,0 mg/m^3	
Singapore	1,0 mg/m^3	3,0 mg/m^3	
South Korea	1,0 mg/m^3	3,0 mg/m^3	
Spain	1,0 mg/m^3	2,0 mg/m^3	
Sweden	0,1 mg/m^3	3,0 mg/m^3	
Switzerland	1,0 mg/m^3	2,0 mg/m^3	
The Netherlands	1,0 mg/m^3	2,0 mg/m^3	
USA	1,0 mg/m^3	2,0 mg/m^3	
United Kingdom	1,0 mg/m^3	2,0 mg/m^3	

Other exposure limits

DNEL (Derived no effect level)					
Substance	**Parameter**	**Exposure**	**Value**	**Population**	**Effects**
Phosphoric acid	DNEL	Long term inhalation	1,0 mg/m^3	Workers	Local effects

8.2. Exposure controls

Appropriate engineering controls

The usual precautionary measures are to adhered to when handling chemicals.
Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Hygiene measures: Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before re-use. Provide eyewash equipment and safety showers close to the working place.

Eye/face protection: Wear safety glasses with side-shields or goggles conforming to EN 166.

Skin protection: Hand protection:
Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374.
Mean Breakthrough Time > 480 min.

Body protection:
Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved.
Change contaminated clothing immediately.

Respiratory protection: Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system.
If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN13487).

Environmental exposure controls

Every waste disposal must be in compliance with national and local regulations.
Avoid release into soil, water supplies or sewage system.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical appearance:	STOP SOLUTION is a clear, colourless liquid.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	No data available.
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid,gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

9.2. Other information

No further information available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity
Exothermic reactions with water.

10.2. Chemical stability
Stable under normal temperatures and pressures. Stable until expiry date stated on label when stored as directed.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

10.5. Incompatible materials
Reacts violently in contact with strong alkalis. May produce hydrogen gas in contact with reactive metals (steel aluminium,…).

10.6. Hazardous decomposition products
Hazardous thermal decomposition products in small quantities, i.e. phosphorous oxides are possible in a fire.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
There are no toxicological data available for the STOP SOLUTION as a mixture.
However, one can consider the effects of exposure to the individual hazardous component of the mixture, i.e. phosphoric acid, to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Phosphoric acid**:

Acute toxicity:

Acute toxicity data for Phosphoric acid	
LD_{50},oral, rat	1930,0 mg/kg
LD_{50},dermal, rabbit	2740,0 mg/kg

Corrosion/Irritation:

Eye contact: Causes severe eye irritation.
Ingestion: Maybe harmful if swallowed.
Inhalation: No information available.
Skin contact: Causes skin burns.

Sensitization: No data available.

Germ cell mutagenicity: Lack of data.

Carcinogenicity: Phosphoric acid is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v).

Mutagenicity: Lack of data.

Reproductive toxigenicity: Lack of data..

Specific target organ toxicity:
– **single exposure** Lack of data.

Specific target organ toxicity:
– **repeated exposure** Lack of data.

Aspiration hazard: Lack of data..

Signs and symptoms of exposure:

Corrosive and irritant in case of skin contact. Inflammation or blistering of skin is possible. Eye contact may result in serious eye irritation. Avoid breathing dust/fume/gas/mist /vapour/spray.

11.2. Additional toxicological information
Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12 - ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of STOP SOLUTION as a mixture are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for Phosphoric acid used in the formulation of the STOP SOLUTION:

Eco-toxicity data for Phosphoric acid
No data available

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Other adverse effects

No information available.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Every waste disposal must be in compliance with national and local regulations.
Observe all Federal, Regional and Local legislation concerning health and pollution.
Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging

Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as the product.

SECTION 14 - TRANSPORT INFORMATION

This product contains no hazardous materials subjected to Transport Regulations.

Land transport (road/rail) ADR/RID:	No limitations
Maritime transport (sea) IMDG:	No limitations
Air transport (air) ICAO/IATA:	No limitations

14.1. UN number

ADR/RID: n/a IMDG: n/a IATA: n/a

14.2. UN proper shipping name

ADR/RID: n/a IMDG: n/a IATA: n/a

14.3. Transport hazard class(es)

ADR/RID: n/a IMDG: n/a IATA: n/a

14.4. Packing group

ADR/RID: n/a IMDG: n/a IATA: n/a

14.5. Environmental hazards

ADR/RID: no IMDG: no IATA: 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.

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

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15.2. Chemical safety assessment

No data available.

SECTION 16 - OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol	
	GHS05 – Danger/Warning - Corrosive

Hazard Statements	
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary Statements	
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Abbreviations used in the text

ACGIH : American Conference of Governmental Industrial Hygienists.
ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road.
CPS : Chemical Abstracts Service.
CLP : Classification, Labelling, Packaging.
GHS : Globally Harmonized System of Classification and Labelling of Chemicals.
IARC : International Agency for Research on Cancer.
IATA : International Air Transport Association.
IATA-DGR : Dangerous Goods Regulation by IATA.
ICAO : International Civil Aviation Organization.
IMDG : International Maritime Code for Dangerous Goods.
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REACH : Registration, Evaluation, Authorization and Restriction of Chemicals.
RID : Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL : Short Term Exposure Limit.
TWA : Time Weighted Average 8 hours day.

Further information

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Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated,, they may present unknown hazards and should be used with caution. The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.