

# SAFETY DATA SHEET

## EULISA kits

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

<b>PRODUCT NAME / CODE:</b>	EULISA Cardiolipin IgA	212996
	EULISA Cardiolipin IgG	212796
	EULISA Cardiolipin IgM	212896
	EULISA $\beta$ 2-Glycoprotein-1 IgA	212696
	EULISA $\beta$ 2-Glycoprotein-1 IgG	212496
	EULISA $\beta$ 2-Glycoprotein-1 IgM	212596
	EULISA dsDNA IgG	212196
	EULISA RNP IgG	213296
	EULISA Sm IgG	213396
	EULISA Ro (SS-A) IgG	213496
	EULISA La (SS-B) IgG	213596
	EULISA Scl-70 IgG	213196
	EULISA CENP-B IgG	213696
	EULISA Jo-1 IgG	213796
	EULISA ANA Profile 8 IgG	213096
	EULISA ANA Screen 6 IgG	214096
	EULISA ANA Screen 8 IgG	213896
	EULISA TG IgG	211996
	EULISA TPO IgG	212096
	EULISA MPO ANCA IgG	211596
	EULISA PR3 ANCA IgG	211696
	EULISA GBM IgG	212296
	EULISA Modified Gliadin Peptide IgA	215196
	EULISA Modified Gliadin Peptide IgG	215096
	EULISA tissue-Transglutaminase IgA	211796
	EULISA tissue-Transglutaminase IgG	212396
	EULISA eTG IgA	215296
	EULISA Helicobacter pylori IgG	211396
	EULISA Helicobacter pylori IgA	211296
<b>Product description</b>	<b>Kit consisting of following reagents:</b> <ul style="list-style-type: none"> <li>• Reagent A: Wash buffer (10x Conc.)</li> <li>• Reagent B: Sample buffer</li> <li>• Reagent C: Conjugate</li> <li>• Reagent D: Calibrator 1 - 6</li> <li>• Reagent E: Positive Control</li> <li>• Reagent F: Negative Control</li> <li>• Reagent G: Substrate TMB (separate SDS available on request)</li> <li>• Reagent H: Stop Solution</li> <li>• Antigen coated plate</li> </ul>	

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

<b>Use of the product</b>	Kit consisting of different reagents for in vitro diagnostic and research use.
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#### 1.3 Details of the supplier of the safety data sheet

<b>Company</b>	Euro Diagnostica AB
<b>Address</b>	Lundavägen151
<b>Zip code/Olace</b>	SE-212 24 Malmö, Sweden
<b>Telephone</b>	+46 40 53 76 00
<b>Internet</b>	<a href="http://www.eurodiagnostica.com">www.eurodiagnostica.com</a>
<b>E-mail</b>	<a href="mailto:info@eurodiagnostica.se">info@eurodiagnostica.se</a>

#### 1.4 Emergency telephone number

Emergency telephone no.	+46 20 996000 - Poisson Information Centre, Sweden
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## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

**Product definition:** In vitro diagnostic kit and research use kit consisting of different reagents.

#### Classification according to the Directive 1999/45/EC (DPD)

**Reagent A, B, C, D, E, F, G, H and the antigen coated plate:** Not classified as dangerous.

#### Classification according to the Regulation (EC) No. 1272/2008 (CLP)

**Reagent A, B, C, D, E, F, G, H and the antigen coated plate:** Not classified as dangerous.

### 2.2 Label elements according to the Regulation (EC) No. 1272/2008 (CLP)

**Reagent A, B, C, D, E, F, G, H and the antigen coated plate:** No labeling required.

### 2.3 Special labelling of certain preparations

**Reagent H:** Safety data sheet available for professional user on request.

### 2.4 Other hazards

<b>Other hazards which do not result in classification</b>	None
<b>Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII</b>	PBT: No (refers to substances containing)
<b>Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII</b>	vPvB: No (refers to substances containing)

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Reagents containing following substances classified as dangerous

Reagent	Ingredient name	EC-number	CAS-number	REACH registr. number	Conc.	Classification 67/548/EEC	Classification Regulation (EC) No. 1272/2008 [CLP]
A: Wash buffer (10x-Conc.)	5-Bromo-5-nitro-1,3-dioxan	250-001-7	30007-47-7	--	<0,15% (w/v)	R34 S26; S28	Skin corr./irrit. 1B Eye dam./irrit. 1 Aquatic chronic 1
B: Sample buffer	Sodium azide	247-852-1	26628-22-8	--	0,025% (w/v)	T+; R28, R32 N; R50/53	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032
C: Conjugate	5-Bromo-5-nitro-1,3-dioxane	250-001-7	30007-47-7	--	<0,01% (w/v)	R34 S26; S28	Skin corr./irrit. 1B Eye dam./irrit. 1 Aquatic chronic 1
	2-Methyl-4-isothiazolin-3-one	220-239-6	2682-20-4	--	<0,01 (w/v)	T, C, N; R23/24/25, 34, 43 50/53	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens.1, H317 Acute Tox 2, H331 Aquatic Chronic 1, H410
D: Calibrator 1 - 6	Sodium azide	247-852-1	26628-22-8	--	0,025% (w/v)	T+; R28, R32 N; R50/53	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032
E: Positive Control	Sodium azide	247-852-1	26628-22-8	--	0,025% (w/v)	T+; R28, R32 N; R50/53	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

Reagent	Ingredient name	EC-number	CAS-number	REACH registr. number	Conc.	Classification 67/548/EEC	Classification Regulation (EC) No. 1272/2008 [CLP]
F: Negative Control	Sodium azide	247-852-1	26628-22-8	--	0,025% (w/v)	T+; R28, R32 N; R50/53	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032
Additional information: The calibrators (D) and controls (E, F) contain material of human origin which has produced negative results when tested for the presence of hepatitis B surface (HBs) antigen and antibodies to human immunodeficiency virus (HIV) 1/2 and hepatitis C virus (HCV) by FDA-approved or European Directive 98/79/EC-compliant tests. However, since no test method offers complete assurance that infectious agents are absent, these reagents should be treated as potentially infectious and discarded appropriately.							
G: Substrate TMB	3,3',5,5'-Tetra-methylbenzidine	259-364-6	54827-17-7	--	<0,02% (w/w)	Xn; R22 N; R51 53	Acute Tox. 4; H302 Aquatic Chronic 2; H411
H: Stop Solution	Sulphuric acid (H <sub>2</sub> SO <sub>4</sub> )	231-639-5	7664-93-9	--	4,2% (w/w)	C; R35	Skin corr. 1A; H314
The antigen coated plate contains no dangerous substances. See section 16 for the full text of the classifications declared above. Occupational exposure limits are mentioned under section 8, if such exists.							

#### 4. FIRST AID MEASURES

##### 4.1 Description of first aid measures

<b>Inhalation</b>	Remove to fresh air, rest. Call a physician if the complaints persist.
<b>Skin contact</b>	Remove contaminated clothing and footwear. Wash the skin properly with soap and water.
<b>Eye contact</b>	Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if the complaints persist.
<b>Ingestion</b>	Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of milk/water to dilute the substance in stomach. Call a physician if the complaints persist.

##### 4.2 Most important potential symptoms and health effects, both acute and delayed

<b>Inhalation</b>	Exposure to high airborne concentrations of the reagents in this kit may cause irritation in the respiratory tract, dizziness and sickness.
<b>Skin contact</b>	Not relevant.
<b>Eye contact</b>	Not relevant.
<b>Ingestion</b>	Ingestion of larger amounts may cause sickness and vomiting.

##### 4.3 Indication of any immediate attention and special treatment needed

<b>Ingestion</b>	Treat symptomatically.
<b>Specific treatments</b>	No specific treatment.

#### 5. FIRE-FIGHTING MEASURES

##### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	Dry chemical, foam, water spray or carbon dioxide
<b>Unsuitable extinguishing media</b>	Waterjet

##### 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	None
<b>Hazardous thermal decomposition products</b>	Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases.

##### 5.3 Advice for fire-fighters

<b>Special protective actions for fire-fighters</b>	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
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<b>Special protective equipment for fire-fighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
<b>Further information</b>	Not applicable

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	No action will be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.
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<b>For emergency responders</b>	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.
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### 6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### 6.3 Methods and materials for containment and cleaning up

<b>Small spill</b>	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
<b>Large spill</b>	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with noncombustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

### 6.4 Reference to other sections

<b>Reference to other sections</b>	See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.
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## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

<b>Protective measures</b>	Put on appropriate personal protective equipment (see Section 8).
<b>Advice on general occupational hygiene</b>	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### 7.2 Conditions for safe storage, including any incompatibilities

<b>Storage</b>	Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10), food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.
<b>Further information</b>	Not applicable

### 7.3 Specific end use(s)

Reagents for in vitro diagnostic and research use.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

#### Occupational exposure limits

Chemical name	European Union	United Kingdom	France	Spain	Germany
<b>Sodium Azide</b> (CAS No. 26628-22-8)	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin	VME: 0.1 mg/m <sup>3</sup> VLCT: 0.3 mg/m <sup>3</sup>	VLA-EC: 0.3 mg/m <sup>3</sup> VLA-ED: 0.1 mg/m <sup>3</sup>	MAK: 0.2 mg/m <sup>3</sup> Ceiling / Peak: 0.4 mg/m <sup>3</sup> TWA: 0.2 mg/m <sup>3</sup>
	<b>Italy</b> TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin	<b>Portugal</b> Ceiling: 0.29 mg/m <sup>3</sup> Ceiling: 0.11 ppm	<b>Netherlands</b> TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin	<b>Finland</b> TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin	<b>Denmark</b> TWA: 0.1 mg/m <sup>3</sup> Skin
	<b>Austria</b> MAK: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin	<b>Switzerland</b> MAK: 0.2 mg/m <sup>3</sup> STEL: 0.4 mg/m <sup>3</sup>	<b>Poland</b> NDSch: 0.3 mg/m <sup>3</sup> NDS: 0.1 mg/m <sup>3</sup> Skin	<b>Norway</b> Ceiling: 0.3 mg/m <sup>3</sup> Skin	<b>Ireland</b> TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin

Chemical name	European Union	United Kingdom	France	Spain	Germany
<b>Sulphuric Acid</b> (CAS No. 7664-93-9)	0.05 mg/m <sup>3</sup> thoracic fraction	--	0.05 mg/m <sup>3</sup> thoracic fraction	VLA-EC: 2 mg/m <sup>3</sup>	MAK: 0.1 mg/m <sup>3</sup> inhalable aerosols STEL: 0.1 mg/m <sup>3</sup>
	<b>Italy</b> TWA: 0.05 mg/m <sup>3</sup>	<b>Sweden</b> TWA: 0.1 mg/m <sup>3</sup> STEL: 0.2 mg/m <sup>3</sup>	<b>Netherlands</b> 0.05 mg/m <sup>3</sup> thoracic fraction	<b>Finland</b> --	<b>Denmark</b> TWA: 1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
	<b>Austria</b> MAK: 1 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup> inhalable aerosols	<b>Switzerland</b> MAK: 0.1 mg/m <sup>3</sup> STEL: 0.1 mg/m <sup>3</sup> inhalable aerosols	<b>Poland</b> NDSch: 1 mg/m <sup>3</sup> NDS: 3 mg/m <sup>3</sup>	<b>Norway</b> --	<b>Ireland</b> --

<b>Recommended monitoring</b>	Not relevant
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#### Derived effect levels

Product /	Type	Exposure	Value	Population	Effects
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<b>Predicted effect concentrations</b>	Not available
<b>PNEC Summary</b>	Not available

### 8.2 Exposure controls

<b>Appropriate engineering controls</b>	Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.
<b>Hygiene measures</b>	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
<b>Respiratory protection</b>	Not relevant during normal condition.
<b>Eye / face protection</b>	Safety glasses or face shield shall be worn.
<b>Hand protection</b>	Chemical-resistant, impervious gloves in butyl rubber or nitril rubber complying with an approved standard shall be worn.
<b>Body protection</b>	Wear suitable protective clothing.
<b>Environmental exposure controls</b>	Not applicable

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties of the reagents

Property	Reagent A	Reagent B	Reagent C	Reagent D	Reagent E	Reagent F	Reagent G	Reagent H
<b>Physical state</b>	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
<b>Colour</b>	Blue	Orange	Green, red or yellow	Colourless or blue	Red	Green	Colourless	Colourless
<b>Odour</b>	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
<b>Odour threshold</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Solubility(ies)</b>	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water
<b>pH (product)</b>	near neutral	near neutral	near neutral	near neutral	near neutral	near neutral	near neutral	< 0.5
<b>Melting point / freezing point</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Initial boiling point and boiling range</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Flash point</b>	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C
<b>Evaporation rate (butyl acetate = 1)</b>	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1
<b>Flammability (solid, gas)</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Upper / lower flammability or explosive limits</b>	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.	Upper: n.a. Lower: n.a.
<b>Combustion rate</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Vapour pressure (at 20°C)</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Vapour density</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Relative density (water = 1)</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Partition coefficient: n-octanol / water</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Autoignition temperature</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Decomposition temperature</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Viscosity</b>	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
<b>Explosive properties</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Oxidizing properties</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not applicable n.d. = not determined

### 9.2 Other information

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## 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	Non-reactive
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<b>10.2 Chemical stability</b>	Stabile under normal conditions of use and storage.
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<b>10.3 Possibility of hazardous reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
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<b>10.4 Conditions to avoid</b>	Avoid direct sunlight.
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<b>10.5 Incompatible materials</b>	None
<b>10.6 Hazardous decomposition products</b>	Carbon monoxide, carbon dioxide and nitrous gases

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

Assessment of acute toxicity for the different reagents:

Not harmful if inhaled. Not harmful in contact with skin. Not harmful if swallowed.

Calculated data:

LD50 oral, rat: > 2000 mg/kg

LD50 dermal, rat: > 2000 mg/kg

#### Irritation / Corrosion

Assessment of irritating effect for the different reagents

Experimental / calculated data:

Corrosive or irritating to the skin, rabbit: Not irritating

Serious eye damage / eye irritation, rabbit: Not irritating

#### Sensitization by inhalation / skin contact

Assessment of sensibility for the different reagents:

May not cause any sensitizing effects.

#### Germ cell mutagenicity

Assessment of mutagenicity for the different reagents:

The chemical structure of the different reagents don't indicate any mutagenic effects.

#### Carcinogenicity

Assessment of carcinogenicity for the different reagents:

The chemical structure of the different reagents don't indicate any carcinogenic effects.

#### Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:

The chemical structure of the different reagents don't indicate any reproduction toxic effects.

#### Developmental toxicity

Assessment of developmental toxicity for the different reagents:

The chemical structure of the different reagents don't indicate any teratogenic effects.

#### Specific target organ toxicity (single exposure)

STOT assessment single dose toxicity:

Based on available information, an organ specific toxicity is not expected for the different reagents.

#### Repeated dose toxicity and specific organ toxicity (repeated exposure)

Based on available information, an organ specific toxicity is not expected for the different reagents.

## 12. ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### 12.1.1 Acute toxicity in the aquatic environment of sodium azide

Test	Value / unit (mg/L)	Test method	Exp. time (h)	Species
Fish LC50	0.8 - 1.6	--	96	Rainbow trout
Daphnia EC50	4.2	--	48	Daphnia pulex
Not readily biodegradable.				

**12.1.2 Acute toxicity in the aquatic environment of 2-methyl-4-isothiazolin-3-one**

Test	Value / unit (mg/L)	Test method	Exp. time (h)	Species
Daphnia EC50	0.18	--	48	Daphnia magna
BCF = 114. Log <sub>OW</sub> : -0.486. Bioaccumulating effects are not expected. 48-54% degraded in 29 days OECD 301B. Not readily biodegradable.				

**12.1.3 Acute toxicity in the aquatic environment of 5-bromo-5-nitro-1,3-dioxan**

Test	Value / unit (mg/L)	Test method	Exp. time (h)	Species
Fish LC50	> 1 - 10	--	--	--
ECO50	> 1 - 10	--	--	Microorganisms
Assessment biodegradation and elimination (H <sub>2</sub> O): The organic component of the product is biodegradable.				
Assessment bioaccumulation potential: No data available.				

**12.1.4 Acute toxicity in the aquatic environment of 3,3',5,5'-tetramethylbenzidine (TMB)**

Test	Value / unit (mg/L)	Test method	Exp. time (h)	Species
EC50	1 - 10 (EPI-suite model)	--	--	--
Persistence and degradability: TMB is predicted not to be easily biodegradable (EPI-suite model).				
Bioaccumulation potential: Log <sub>OW</sub> = 4.11 - bioaccumulation is expected.				

**12.1.5 Acute toxicity in the aquatic environment of all reagents (calculated)**

Test	Value / unit (mg/L)	Test method	Exp. time (h)	Species
Fish LC50	> 100	--	96	--
Daphnia EC50	> 100	--	48	Daphnia magna
Algae IC50	> 100	--	72	Green algae

**12.1.6 Ecotoxicity**

The reagents contain low concentrations of the above mentioned substances. These concentrations are below the lowest concentration limit for classification as harmful to aquatic organisms.

**12.2 Persistence and degradability**

Conclusion / Summary
The reagents as such will be classified as readily biodegradable.

**12.3 Bioaccumulative potential**

Conclusion / Summary
The reagents as such will not be classified as bioaccumulative.

**12.4 Mobility in soil**

<b>Soil / water partition coefficient (KOC)</b>	Not available.
<b>Mobility</b>	Not available.

**12.5 Results of PBT and vPvB assessment**

<b>PBT</b>	Not applicable.
<b>vPvB</b>	Not applicable.

**12.6. Summary - ecological information**

Conclusion
The reagents contain substances classified as dangerous for the environment. But the concentrations of these substances are very low, so the reagents as such are not classified as dangerous for the environment, according to the EU classification rules in force.
The antigen coated plate is not classified as dangerous for the environment.



### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

##### Product

<b>Method of disposal</b>	The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional authority requirements.  Used kit may be potentially infectious material and shall be disposed as a hazardous waste.
<b>Hazardous waste</b>	Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EU.

##### European waste catalogue (EWC)

EWC Waste Code	Type of waste
18 01 06*	Chemicals consisting of or containing dangerous substances
15 01 10*	Packaging containing residues of or contaminated by dangerous substances

##### Packaging

Method of disposal	Incineration
Special precautions	None

### 14. TRANSPORT INFORMATION

Product classified as dangerous goods:                      Yes                      No                      Not decided  
                                               

	ARD / RID	ADN / ADNR	IMDG	IATA
<b>14.1 UN number</b>	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2 UN proper shipping name</b>	--	--	--	--
<b>14.3 Transport hazard class(es)</b>	--	--	--	--
<b>14.4 Packing Group</b>	--	--	--	--
<b>14.5 Environmental hazards</b>	--	--	--	--
<b>14.6 Special precautions for user</b>	Not available	Not available	Not available	Not available
<b>Additional information</b>	Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.			

#### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

### 15. REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH)

<b>REACH Status</b>	In compliance. Pre-registration status: All components are listed or exempted.
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#### Annex XIV - List of substances subject to authorization

##### Substances of very high concern

None of the components are listed.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles**

Not applicable.

**15.2 Chemical Safety Assessment**

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

## 15.3. Other information

<b>Tariff Code - harmonized system</b>	Not applicable
<b>The EU Seveso Directive</b>	Not applicable

**International regulations**

<b>Chemical Weapons Convention List Schedule I Chemicals</b>	<b>Chemical Weapons Convention List Schedule II Chemicals</b>	<b>Chemical Weapons Convention List Schedule III Chemicals</b>
Not regulated	Not regulated	Not regulated

**15. OTHER INFORMATION**
**Conforms to Regulation (EC) No. 1907 / 2006 (REACH), Annex II**

**Disclaimer:** The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose) is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.

The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

**THE PRODUCER'S NOTES**
**LIST OF R-PHRASES MENTIONED UNDER SECTION 3**

<b>No.</b>	<b>R-Phrases</b>
R22	Harmful when swallowed
R23 / 24 / 25	Toxic by inhalation / In contact with skin / If swallowed
R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R34	Causes burns.
R35	Causes severe burns.
R43	May cause sensitisation by skin contact.
R50	Very toxic to aquatic organisms.
R51	Toxic to aquatic organisms.
R53	May cause long-term adverse effects in the aquatic environment.

**LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3**

<b>No.</b>	<b>H-Statements</b>
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long-lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

**Revisions**

<b>Version</b>	<b>Valid from (date)</b>	<b>Changes</b>
00EN	March 31, 2015	New SDS according to regulation (EC) No. 1907 / 2006 (REACH), Annex II. Replaces Version 1.0, dated February 12, 2013