

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

#### PRODUCT:

**DIACHECK Anti-ZIKAVirus IgG, IgM, IgA**

**REF ZKV – 116, ZKV- 216, ZKV-316 Components No. 1, 2, 3, 4, 5, 6, 7, 8/9, 10 and 11**

#### PRODUCT components

No.	Description	Pieces/Volume	SYMBOL
No. 1	Antigen coated plate/strips	1 Plate (12x8 wells)	Ag   SORB
No. 2	Negative Control	0.6 ml	NEG   -
No. 3	Differential Control	1.2 ml	DC   -/+
No. 4	Positive Control	0.6 ml	POS   +
No. 5	Diluent buffer	20 ml	BUF
No. 6	Additive for No. 5	2 ml	ADD
No. 7	Enzyme Conjugate solution	6 ml	CONJ   IgX
No. 8/9	Substrate / TMB-Chromogen solution	6 ml	SUBS   TMB
No. 10	Wash solution 25x conc.	20 ml	WASH.
No. 11	Stop solution 1% Sulfuric acid	15 ml	STOP.

#### Component No. 1

Description: ZIKAVIRUS Antigen-coated microplate 12 strips with 8 breakable individual wells.  
No.1

Symbol: Ag | SORB

#### Component No. 2, 3, 4

Description: No 2 Negative Control, No 3 Differential Control, No.4 Positive Control.

Symbol: No. 2 NEG | -, No. 3 DC | -/+, No. 4 POS | +

#### Component No. 5, 6, 10

Description: No.5 Diluent buffer, No. 6 Additive for No.5, No. 10 Wash solution 25x conc.

Symbol: No.5 BUF | , No.6 ADD | ,No.10 WASH. |

#### Component No. 7

Description: No.7 Conjugate solution.

Symbol: No.7 CONJ | IgG, IgM, IgA

#### Component No. 8/9, 11

Description: No.8/9 Substrate/TMB-Chromogen solution, 11 Stop solution, corrosive.

Symbol: No.8/9 SUBS | TMB | ,No.11 STOP |

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

Identified uses: *In-vitro* diagnostic use for Product with components 1-11

### 1.3 Details of the supplier of the safety data sheet

Dr. Julio Moran Laboratorien, Lohwisstrasse 32, CH-8123 Ebmatingen (Zurich), Switzerland  
Lab. Tel: +41 44 9800111 Fax: +41 44 9800133 Office Tel: +41 44 9151259 Fax: +41 44 9151250  
Website: www.jmlab.ch e-mail: info@jmlab.ch / julio@jmlab.ch

### 1.4 Emergency telephone number

Manufacturer +41 (0)44 980 0111 (Monday to Friday, 9:00 am to 4:00 pm)

Swiss toxicological information center ( <http://www.toxi.ch/eng/welcome.html> )

**Emergency Phone 145 (24 h, +41 44 251 5151 from outside Switzerland)**

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Product Components No. 1-11

##### Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

##### Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

### 2.2 Label elements

#### Product, Components No. 1-11

This product must not be labelled in accordance to EC directives or respective national laws.

### 2.3 Other hazards

#### Product, Components No. 1-11

This product is not classified as PBT or vPvB.

#### Product, Components No. 2-4

These components contain material of human origin; potentially infectious.

These components are not classified as PBT or vPvB.

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## SECTION 3: Composition/information on ingredients

### Product, Components No. 1-11

#### 3.1 Composition

Components 1-11.

#### 3.2 Ingredients

##### Components 2-4, 6

###### SODIUM AZIDE

CAS-No. 26628-22-8; EC-No: 247-852-1; EINECS Annex I: 011-004-00-7

Concentration: < 0,1 % w/w

##### Classification (67/548/EEC or 1999/45/EC):

T+; R28-R32 N; R50/53

##### Classification (Regulation (EC) No. 1272/2008):

H300, H400, H410

##### Product, Component No. 7

###### ProClin 300

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) 3% in Propylene Glycol.

CAS-No. 55965-84-9; EC-No: 247-500-7 and 220-239-6;

Concentration: < 0.5 % w/w

##### Classification (67/548/EEC or 1999/45/EC):

T, C, N; R 23/24/25-34-43-50/53

##### Classification (Regulation (EC) No. 1272/2008):

H314, H301, H311, H317, H331, H410

##### Product, Component No. 8/9

###### TMB 3,3',5,5'-TETRAMETHYLBENZIDINE

CAS-No.: 54827-17-7; EC-No.: 259-364-6; EINECS Annex I: 016-020-00-8

Concentration: < 1.46 mmol/L

##### Classification (67/548/EEC or 1999/45/EC):

T, C, N; Xi; R36/37/38

##### Classification (Regulation (EC) No. 1272/2008):

H315, H319, H335

##### Product, Component No. 8/9, 10

## Material safety data sheet following (EC) No. 1907/2006 Annex II

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THIOMERSAL

CAS-No.: 54-64-8; EC No.: 200-210-4

Concentration: < 0.05%

**Classification according to Directive 67/548/EEC**

T, C, N; R26/27/28, R33, R50.

**Classification (Regulation (EC) No. 1272/2008)**

H373, H410.

### Product, Component No. 11

Sulfuric acid, corrosive.

CAS-No.: 7664-93-9; EC-No.: 231-639-5; EINECS Annex I: 016-020-00-8

Concentration < 1 % w/w Skin Corr. 1A

**Classification (67/548/EEC or 1999/45/EC):**

T, C, N : C R35

**Classification (Regulation (EC) No. 1272/2008):** H314

**There are no ingredients contained in the components of the PRODUCT:**

**DIACHECK Anti-ZIKAVirus IgG, IgM, IgA**

**which are classified as harmful or polluting in the contained concentrations according to the actual state of knowledge of the manufacturer. The product is not hazardous in the sense of the directive 67/548/EC.**

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## SECTION 4: First aid measures

Product, components No. 1-11

### 4.1 Description of first aid measures

After eye contact:

Flush eyes with plenty of water for at least 15 minutes, remove any contact lenses and continue flushing until medical care can be obtained.

After inhalation:

Fresh air. Consult medical care if cough or other symptoms appear.

After ingestion:

Flush mouth with water, without swallowing, consult medical care or contact the local Poison Control Centre if symptoms develop or persist. Do not induce vomiting unless advised by a Poison Centre or doctor, then provided the victim is conscious, wash out mouth with water and give water to drink.

After skin contact:

Flush contaminated skin with plenty of water if necessary use a disinfectant.

Cloth contamination:

Remove contaminated clothing. If skin contact also occurs, flush contaminated skin with plenty of water, if necessary use a disinfectant. Consult physician if feeling unwell.

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

Unconsciousness, dizziness, headache, nausea, vomiting, CNS symptoms.

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

No information available.

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## SECTION 5: Firefighting measures

Product, components No. 1-11

### 5.1 Extinguishing media

Suitable media: Carbondioxyd (CO<sub>2</sub>), powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Non suitable media: No limitation of appropriate extinguishing media is given.

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### 5.2 Special exposure hazards arising from product components

Components 1-11 are not combustible. Potential formation of toxic pyrolysis products. Nitrogen oxides (NOx) from sodium azide containing components.

### 5.3 Special protective equipment for fire-fighters

Enter the danger area only with self-contained breathing apparatus and wear protective clothing that are appropriate to local circumstances.

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## SECTION 6: Accidental release measures

### Product, components 1-11

#### 6.1 Personal precautions, environmental precautions and cleaning up procedures

##### 6.1.1 Personal precautions

No action shall be taken involving any personal risk or without suitable training. Do not touch or walk through split material. As a general rule do not inhale vapours and aerosols. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures.

Use protective equipment (see section 8).

##### 6.1.2 Environmental precautions

Do not empty into drains. Cover drains. Do not allow to enter sewers/ surface or ground water.

##### 6.1.3 Cleaning up procedures

Absorb spills with liquid binding material. Observe possible material restrictions (see sections 7 and 10). Dispose of properly. Clean up the affected area.

#### 6.2 Additional information

Indications about waste treatment see section 13.

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## SECTION 7: Handling and storage

### Product, components 1-11

#### 7.1 Precautions for safe handling

##### 7.1.1 Advice on safe handling

Observe working precautions using appropriate personal protective equipment (see section 8).

##### 7.1.2 Hygiene measures

Eating, drinking and smoking should be prohibited in areas where these materials are handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.

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

The kit is shipped at ambient temperature and should be stored +2°C to +8°C. Keep container tightly closed and sealed before use. Keep away from heat or direct sun light. Store away from incompatible materials (see section 10) and food and drink. The storage conditions and stability of the prepared reagents after opening is stated in the corresponding chapters of the instruction for use.

#### 7.3 Specific end use

To be used for *In-vitro* laboratory diagnostic use only.

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## SECTION 8: Exposure controls/personal protection

### Product, components 1-11

#### 8.1 Control parameters

##### INGRIDIENT SODIUM AZIDE

Threshold limit value (Germany)	<b>Exposure limit</b>	0,2 mg/m <sup>3</sup>	2(l);	DFG, EU
IOELV (EC)	<b>Short term:</b>	0,3 mg/m <sup>3</sup>		
	<b>Long term:</b>	0,1 mg/m <sup>3</sup>		
Skin		not available		

##### INGRIDIENT SULFURIC ACID

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<b>Type of exposure limit</b>	Threshold limit value (Germany 2009)
<b>Exposure limit</b>	0.1 mg/ m <sup>3</sup> determined as respirable aerosol fraction
<b>Momentary value</b>	0.2 mg/ m <sup>3</sup> determined as respirable aerosol fraction
<b>Maximum exposure limit</b>	exceeding factor 1, 15 min (mean), 4x/shift, 1 hour interval

## 8.2 Exposure controls

### 8.2.1 Engineering measures

No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

### 8.2.2 Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier. Do not eat, drink or smoke during working periods. Thoroughly wash hands after working periods.

#### 8.2.2.1 Eye/face protection

Safety glasses.

#### 8.2.2.2 Skin protection

##### Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

##### Other protective equipment

Protective clothing.

#### 8.2.2.3 Respiratory protection

Not required.

### 8.2.3 Environmental exposure controls

No special precautionary measures necessary.

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## SECTION 9: Physical and chemical properties

### Product, components 1-11

#### 9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless No. 8/9, 10, 11, blue, No. 5, 7, yellow No. 7, red No. 4, 7, green No. 2, 7, orange No. 3, yellow/orange No. 6.
Odour	odourless
Odour Treshold	not applicable
pH	No. 2-4, 5: 7.2-7.4, No. 8/9 4.3-4.5, No.11: 1.
Melting point	undetermined
Boiling point	undetermined
Flash point	not applicable
Evaporation rate	undetermined
Flammability (solid, gas)	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,0 g/cm <sup>3</sup> at 20 °C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	not applicable
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.

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Oxidizing properties none

## 9.2 Other data

No further information available

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## SECTION 10: Stability and reactivity

Product, components 1-11

### 10.1 Reactivity

See section 10.3.

### 10.2 Chemical stability

The product is chemically stable if used according to specifications.

### 10.3 Possibility of hazardous reactions

Contact with acids may liberate toxic gas. Potential formation of nitrogen oxides (NO<sub>x</sub>).

### 10.4 Conditions to avoid

No information available.

### 10.5 Incompatible materials

Acids, heavy metals.

### 10.6 Hazardous decomposition products

Potential formation of Nitrogen oxides (see section 10.3).

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## SECTION 11: Toxicological information

Product, components 1-11

### 11.1 Information on toxicological effects

#### Acute oral toxicity

#### Acute inhalation toxicity

#### Acute dermal toxicity

#### Skin irritation

#### Eye irritation

#### Sensitisation

#### Germ cell mutagenicity

#### Carcinogenicity

#### Reproductive toxicity

#### Teratogenicity

#### Specific target organ toxicity - single exposure

#### Specific target organ toxicity - repeated exposure

#### Aspiration hazard

#### Mixture

Symptoms: headache, nausea, shock [1]

No information available.

No information available.

May cause skin irritation.

May be harmful if absorbed through skin.

May cause eye irritation.

No information available.

No information available.

No information available.

No information available.

No information available.

No information available.

No information available.

No information available.

### 11.2 Further information

#### Further data:

#### Components

#### Acute oral toxicity

#### Acute dermal toxicity

Quantitative data on the toxicity of this product are not available.

Handle in accordance with good industrial hygiene and safety practice.

Sodium Azide (solid substance):

LD50 rat: 27 mg/kg

LD50 rabbit: 20 mg/kg

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## SECTION 12: Ecological information

Product, components 1-11

### 12.1 Toxicity

No information available.

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### 12.2 Persistence and degradability

Biodegradability: The methods for determining the biological degradability are not applicable

### 12.3 Bioaccumulative potential

No information available.

### 12.4 Mobility in soil

No information available.

### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

### 12.6 Other adverse effects

#### Additional ecological information

Discharge into the environment must be avoided.

#### Ingredients

Sodium Azide (solid substance):

#### Toxicity to fish

LC50 *Lepomis macrochirus*: 0,7 mg/l; 96 h

#### Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia pulex*: 4,2 mg/l; 48 h

#### Biodegradability

The methods for determining biodegradability are not applicable.

#### Bioaccumulation

Bioaccumulation is unlikely.

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## SECTION 13: Disposal considerations

### Product, components 1-11

#### Waste treatment methods

**Recommendation:** Dispose of waste according to applicable local, state, and federal regulations, e.g. 2008/98/EG.

#### Uncleaned packaging:

**Recommendation:** Dispose of packaging according to applicable local, state, and federal regulations. Completely emptied packages can be recycled.

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## SECTION 14: Transport information

### Product, components 1-11

#### 14.1 Land transport ADR/RID (cross-border)

**Remarks:** No dangerous good in sense of this transport regulation.

#### 14.2 Inland shipping ADN:

**Remarks:** No dangerous good in sense of this transport regulation.

#### Maritime transport IMDG:

##### Marine pollutant: No

**Remarks:** No dangerous good in sense of this transport regulation.

#### 14.3 Air transport ICAO-TI and IATA-DGR:

**Remarks:** No dangerous good in sense of this transport regulation.

#### Transport/Additional information:

Not dangerous according to the above specifications.

This product is part of a kit. Information in this section refers to the kit as a whole.

#### 14.4 Transport in bulk according to

Annex II of MARPOL 73/78 and the IBC-Code

Not applicable.

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## SECTION 15: Regulatory information

### Product, components 1-11



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

#### EU regulations

Major Accident Hazard Legislation 96/82/EC:

Directive 96/82/EC does not apply

Occupational restrictions:

Take note of Dir 94/33/EC on the protection of young people at work.

#### National legislation

None known.

### 15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

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## SECTION 16: Other information

### Product, components 1-11

#### Full text of R-phrases and H-Statements referred to under section 3.2:

##### ▪ Relevant R-phrases

R28, Very toxic if swallowed

R32, Contact with acids liberates very toxic gas

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R 23/24/25, Toxic by inhalation, in contact with skin and if swallowed

R34, Causes burns.

R43, May cause sensitisation by skin contact

R36/37/38, Irritating to eyes, respiratory system and skin.

R35, Causes severe burns.

##### ▪ Relevant H-statements

H300, Fatal if swallowed

H400, Very toxic to aquatic life

H410, Very toxic to aquatic life with long lasting effects

H314, Causes severe skin burns and eye damage

H301, Toxic if swallowed

H311, Toxic in contact with skin

H317, May cause an allergic skin reaction

H331, Toxic if inhaled

H315, Causes skin irritation

H319, Causes serious eye irritation

H335, May cause respiratory irritation

H373, May cause damage to organs through prolonged or repeated exposure

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Dr. Julio Moran Laboratorien, shall not be held liable for any damage resulting from handling or from contact with the product. The information contained in this Material Safety Data Sheet (MSDS) is current as of the Issue Date shown in Section 1.6 of this document and may be subject to amendment by . Dr. Julio Moran Laboratorien. This MSDS is provided at the best of our knowledge and is subject to reviews including changes and corrections.