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

Dr. Julio Moran, Laboratorien, Vordergrüt 30, CH-8704 Herrliberg (Zurich), Switzerland

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	POSI +
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.

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

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.

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.

SECTION 5: Firefighting measures
Product, components No. 1-11
5.1 Extinguishing media
Suitable media: Carbondioxyd (CO_2), 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.

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.

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 inhalate 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.

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.

SECTION 8: Exposure controls/personal protection
Product, components 1-11
8.1 Control parameters
INGRIDIENT SODIUM AZIDE

Treshold limit value (Germany)	**Exposure limit**	0,2 mg/m³	2(I);	DFG, EU
IOELV (EC)	**Short term:**	0,3 mg/m³		
	Long term:	0,1 mg/m³		
Skin	not available			

INGRIDIENT SULFURIC ACID

Type of exposure limit	Threshold limit value (Germany 2009)
Exposure limit	0.1 mg/ m³ determined as respirable aerosol fraction
Momentary value	0.2 mg/ m³ determined as respirable aerosol fraction
Maximum exposure limit	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.

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/cm³ 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.

Oxidizing properties	none

9.2 Other data
No further information available

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 (NOx).

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).

SECTION 11: Toxicological information

Product, components 1-11

11.1 Information on toxicological effects	**Mixture**
Acute oral toxicity	Symptoms: headache, nausea, shock [1]
Acute inhalation toxicity	No information available.
Acute dermal toxicity	No information available.
Skin irritation	May cause skin irritation. May be harmful if absorbed through skin.
Eye irritation	May cause eye irritation.
Sensitisation	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
Teratogenicity	No information available.
Specific target organ toxicity - single exposure	No information available.
Specific target organ toxicity - repeated exposure	No information available.
Aspiration hazard	No information available.

11.2 Further information	Quantitative data on the toxicity of this product are not available.
Further data:	Handle in accordance with good industrial hygiene and safety practice.
Components	Sodium Azide (solid substance):
Acute oral toxicity	LD50 rat: 27 mg/kg
Acute dermal toxicity	LD50 rabbit: 20 mg/kg

SECTION 12: Ecological information

Product, components 1-11

12.1 Toxicity
No information available.

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.
Ingridients
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.

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.

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.

SECTION 15: Regulatory information
Product, components 1-11

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.

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.