

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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## **1. Identification of the mixture and the company**

### **1.1. Product identity**

**Trade name:** Anti- $\beta_2$  GP-I screen (96 determinations, 12x 8)

**Article no.:** 4036

### **1.2. Use**

Anti- $\beta_2$  GP-I screen is used for the semi-quantitative determination (screening) of IgG, IgM and IgA antibodies to  $\beta_2$  glycoprotein-I ( $\beta_2$  GP-I) in human serum or plasma for the diagnosis of anti-phospholipid antibody syndrome (APAS).

### **1.3. Manufacturer**

GA Generic Assays GmbH  
Ludwig-Erhard- Ring 3  
15827 Dahlewitz  
Tel: +49-(0)33708-9286-0  
Fax: +49-(0)33708-9286-50  
Internet: [www.genericassays.com](http://www.genericassays.com)  
E-mail: [info@genericassays.com](mailto:info@genericassays.com)

### **1.4. Emergency numbers**

GA Generic Assays GmbH      Tel.: +49-(0)033708 9286-0

## **2. Possible hazards**

### **2.1. Classification of the contents**

The product / product components are, in accordance to EU regulation 1272/2008/EG, **classified as non-hazardous.**

### **2.2. Identification elements**

According to 1272/2008/EG: none

### **2.3. Other hazards**

The product/product components contain preservatives, which in the present concentrations can cause skin sensitization and weak water pollution. As there are always certain dangers associated with chemicals, the product/product component should only be handled by appropriately trained persons, using proper chemical safety precautions.

Results of the PBT/vPvB evaluation: not applicable

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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### **3. Composition / Information on ingredients**

#### **3.1. Description of ingredients**

<b>Component</b>	<b>Ingredients</b>	<b>Preservative</b>
Mikrotiter plate	Microtiter plate ,12 breakable strips per 8 wells (total 96 individual wells) coated with highly purified human $\beta_2$ GP-I	
Wash buffer, 10x	TRIS NaCl, KCl Tween 20	0.5% Neolone™ M10
Sample diluentr	Na <sub>2</sub> HPO <sub>4</sub> , KH <sub>2</sub> PO <sub>4</sub> NaCl, Tween 20 BSA	0.1% Neolone™ M10
Conjugate	POD-conjugate	0.1% Neolone™ M10
Substrate	< 0,05% 3,3'5,5'-Tetramethyl-benzidin	
Stop solution	0.25 M Sulfuric acid	
positive, negative, cut-off control	Na <sub>2</sub> HPO <sub>4</sub> , KH <sub>2</sub> PO <sub>4</sub> NaCl, Tween 20 BSA	0.1% Neolone™ M10

#### **3.2. Hazardous components and their concentrations**

<b>CAS No.</b>	<b>EINECS No.</b>	<b>Ingredient</b>	<b>Percent</b>	<b>Classification (in conc. Form) to 1272/2008/EG</b>	
77-86-1	201-064-4	Tris(hydroxymethyl-)aminomethan	<1	Xi	Skin irrit. 2, H315 Eye irrit. 2, H319
2682-20-4	220-239-6	Neolone™ M10*)	0.1-0,5	T C, Xi N Xi	Acute tox. 3, H331, 311, 301 Skin corr. 1B, H314 Skin sens. 1, H317 Eye Dam. 1, H318 Aquatic Acute 1, H400
7664-93-9	231-639-5	Sulfuric acid	0.25M	C	Skin corr. 1A, H314 Met. corr. 1, H290

\*) The preservative Neolone™ M10 contains < 10,0% 2-Methyl-4-isothiazolin-3-on (2682-20-4).

The full wording of the listed hazard warnings is given in section 16.

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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#### **4. First aid measures**

##### **4.1. Description of first aid measures**

Due to the very low concentrations of the hazardous ingredients in the product/components, consultation of a doctor is not necessary.

In cases of contact with skin, wash with copious amounts of water.

In cases of contact with eyes, rinse out for several minutes with water, with eyelids open.

In cases of swallowing, rinse out and drink copious amounts of water.

##### **4.2. Important symptoms and effects**

There are no known acute or delayed onset symptoms and effects.

##### **4.3. Indications for immediate medical assistance and special handling**

Where necessary consult an ophthalmologist.

Wash contaminated clothing before reuse.

#### **5. Fire-fighting measures**

##### **5.1. Extinguishers**

Extinguishers indicated: water spray, foam, powder.

##### **5.2. Special hazards arising from the contents**

Not related

##### **5.3. Notes on firefighting**

Surround the fire with appropriate extinguishing material.

If necessary use breathing apparatus and protective clothing for firefighting.

#### **6. Accidental release measures**

##### **6.1. Personal precautions**

Observe the safety regulations of the laboratory.

To minimize the risk of contact with the skin and eyes, wear appropriate protective clothing. Do not swallow, do not pipette by mouth.

##### **6.2. Environmental precautions**

Do not release into drains/surface water/ground water.

##### **6.3. Methods and materials for containment and cleaning**

Contain spills with absorbent material, and dispose of appropriately. Following complete removal of the material, clean the affected area thoroughly.

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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#### 6.4. Reference to other sections

Information on appropriate protective clothing can be found in section 8.2.  
For disposal, consult section 13.

### 7. Handling and Storage

#### 7.1. Protective measures for safe handling

Apart from the usual laboratory safety regulations, no particular protective measures are required.  
Information on required protective clothing can be found in section 8.2.

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

When well sealed according to instructions on the product components, storage at 2 - 8°C or -20°C

#### 7.3. Specific end-uses

No further relevant information available.

### 8. Exposure controls / personal protection

#### 8.1. Parameters/exposure values to be observed

CAS No.	Ingredient	MAK or AGW (from TRGS 900)
7664-93-9	Sulfuric acid	1 mg/m <sup>3</sup>
77-86-1	TRIS(hydroxymethyl)-aminomethan	no data available
2682-20-4	Neolone™ M10	1.5 mg/m <sup>3</sup>

With appropriate use of the pack/pack contents, no air pollution is expected.

#### 8.2. Limitations and monitoring of exposure

Respiratory protection: Not required  
Gloves: Nitrile or natural latex laboratory gloves  
Eye protection: Safety goggles  
Bodily protection: Appropriate laboratory wear

### 9. Physical and chemical properties

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

Form: kit reagents liquid, microtiter plate solid.  
Color: reddish (sample diluent, conjugate), blue (controls), colorless (wash buffer, substrate, stop solution)  
Odor: odorless  
pH - value: <1 – 7,5  
Melting point / Melting region / boiling point / boiling region / density: not related  
Flash point: not applicable  
Risk of explosion: no risk of explosion

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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## 9.2. Other properties

Solubility in / miscibility with water: complete

## 10. Stability and reactivity

### 10.1. Reactivity

There are no chemical reactive properties of the product / product components

### 10.2. Chemical stability

Within the stated storage temperatures and expiry dates, the product / components are chemically stable.

### 10.3. Possible hazardous reactions

No data available

### 10.4. Conditions to be avoided

Strong light sources can negatively influence the functional ability of the conjugate.

### 10.5. Incompatible materials

Acids, alkalis and solvents can negatively influence the functional ability of the product / components.

### 10.6. Hazardous decomposition products

Within the stated storage and handling conditions, the product / components product no known hazardous decomposition products.

## 11. Toxicological information

### 11.1. Information on toxicological effects

#### Acute Toxicity

Ingredient	Measurant	Value	Species
Sulfuric acid	LD50	2140 mg/kg	rat
TRIS(hydroxymethyl)-aminomethan	LD <sub>50</sub> (oral)	5900 mg/kg	rat
Neolone™ M10	LD <sub>50</sub> (oral)	2838 mg/kg	rat (male)
Neolone™ M10	LD <sub>50</sub> (oral)	1091 mg/kg	rat (female)
Neolone™ M10	LD <sub>50</sub> (dermal)	>5000 mg/kg	rabbit

#### Other health effects

Ingredient	Irritation and corrosion	Sensitization	CMR Effect
Sulfuric acid	no data available	no data available	no data available
TRIS(hydroxymethyl)-aminomethan	skin, mucosa, eye	none	no data available
Neolone™ M10	skin (rabbit)	yes (dugnea pig)	none

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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## **12. Ecological information**

### **12.1. Toxicity**

<b>Ingredient</b>	<b>Measurand</b>	<b>Value</b>	<b>Species</b>
Sulfuric acid	no data available		
TRIS(hydroxymethyl)-aminomethan	no data available		
Neolone™ M10	LC <sub>50</sub>	10 mg/l/96h	bluegill sunfish
Neolone™ M10	LC <sub>50</sub>	4,77 mg/l/96h	rainbow trout
Neolone™ M10	EC <sub>50</sub>	0,85 mg/l/48h	Daphnia magna
Neolone™ M10	EC <sub>50</sub>	0,22 mg/l	alga (Selenastrum capricornutum)

### **12.2. Persistence and biodegradability**

<b>Ingredient</b>	<b>Measurand</b>	<b>Value</b>	<b>Remarks</b>
Sulfuric acid	LD <sub>50</sub>	10mg /L/96h	toxic to aquatic organisms due to pH shift
TRIS	no data available		
Neolone™ M10	OECD guideline 301B or equivalent	0,32 %	not easily biodegradable
Neolone™ M10	Sludge Respiration Inhibition (EC <sub>50</sub> )	41 mg/l	active substance

### **12.3. Bioaccumulation potential**

No data available

### **12.4. Mobility in soil**

No data available.

### **12.5. Results of PBT and vPvB analyses**

No data available.

### **12.6. Other harmful effects**

Due to the very low concentration of hazardous ingredients in the product / components, no ecological problems are expected arising from their use.

## **13. Disposal considerations**

### **13.1. Disposal methods**

#### **Product components**

May not be disposed of with household waste.

Residues of chemical preparations are usually classed as waste which must be disposed of according to the rules issued by the country and government. Information on the disposal of hazardous waste can be given by the local authorities (agency or authorized waste disposal contractor).

Radioactive material is to be disposed of in special waste containers suited to this purpose.

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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**Packaging**

Disposal according to official regulations.

Contaminated packaging should be treated as per the product.

Non-contaminated packaging can be handled as household waste and be recycled, when regulations do not state otherwise.

**14. Transport information**

This product has no transport regulations

**14.1. UN number**

Not applicable

**14.2. Transport hazard class**

Not applicable

**14.3. Packaging group**

Not applicable

**14.4. Environmental hazard**

Not applicable

**14.5. Special precautions for users**

Not applicable

**14.6. Mass transport in accordance with appendix II MARPOL agreements 73/78 and IBC code**

Not applicable.

**15. Regulatory information**

This safety data sheet fulfils the requirements of regulation 1907/2009/EG on the registration, evaluation, authorization and restriction of chemicals, ( REACH ), and the regulation 1272/2008/EG on the classification, labeling and packaging of chemicals and mixtures, as well as the regulation 830/2015/EG on the production of safety data sheets.

**15.1. Safety, health and environmental regulations/ regulations specific to this substance or mixture**

When handling the product, the current regulations for handling potentially infectious human sample material should be observed.

Product classification to1272/2008/EG: none

**15.2 Chemical safety assessment**

A chemical safety assessment has not been performed.

Document No.: GA-MSDS-4036-E-v01-18-01-29	<b>Safety Data Sheet</b> According to (EU) No.830/2015	
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## **16. Other information**

Full text of risk phrases listed in section 3.2.

H290	May be corrosive to metals
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	Can cause allergic skin reactions
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H400	Very poisonous to water organisms
H410	Very poisonous to water organisms with long-term effects

## **Abbreviations and acronyms**

AGW	Arbeitsplatzgrenzwert (workplace limit)
AP	Alkaline Phosphatase
BCIP	Bromo-Chloro-Indolyl-Phosphate
BSA	Bovine serum albumin
CAS	Chemical Abstract Service (division of the American Chemical Society)
CLP	Regulation of Classification, Labelling, and Packaging of Substances and Mixtures
CMR	cancerogenic, mutagenic or reprotoxic
EC50	Effective concentration for 50 % of subjects
EINECS	European Inventory of Existing Commercial Chemical Substances
GHS	Globally Harmonized System of Classification and Labeling of Substances
IBC-Code	International Code for the Construction and Equipment of Ships carrying dangerous Chemicals in Bulk
IARC	International Agency for Research on Cancer
LD50	Lethal dose for 50 % of subjects
LC50	Lethal concentration for 50 % of subjects
MAK	Maximale Arbeitsplatzkonzentration (maximum workplace concentration)
MARPOL	International Convention for the Prevention of Pollution from Ships
MIT	MethylIso Thiazolones
NBT	Nitrotetrazolium-Chlorideblue
OECD	Organization for Economic Co-operation and Development
PBT/vPvB	Persistent, bioaccumulative, and toxic substances / very persistent and very bioaccumulative substances
REACH	Registration, Evaluation, and Authorisation of Chemicals
TRGS	Technische Regeln für Gefahrstoffe (technical regulations for hazardous chemicals)
TBS	Tris buffered saline
USDA	US Department of Agriculture

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