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According to (EU) No.830/2015



1. Identification of the mixture and the company

1.1. Product identity

Trade name: GA CoV-2 lgG +

Article no.: 3940 (96 determinations, 12x 8)



www.EagleBio.com

1.2. Use

GA CoV-2 IgG + is an ELISA for the confirmation of samples positive for IgG antibodies to immundominat antigens of CoV-2 in first screening. The test can be used in addition to identify the specificity of antibodies to a certain antigen.

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: <u>www.genericassays.com</u> E-mail: 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

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3. Composition / Information on ingredients

3.1. Description of ingredients

Component	Ingredients	Preservative
Mikrotiter plate	Microtiter plate, 12 breakable strips per 8 wells (total 96 individual wells); coated with recombinant CoV-2 antigens	
Wash buffer, 20x	10 mM phosphate buffer, Tween 20	0.045% ProClin 300
Sample Diluent	1% goat serum, 10 mM sodium citrate, Tween 20	0.045% ProClin 300 0.09% Na-azide
Start reagent	10 mM Tris	0.045% ProClin 300
Conjugate	horseradish peroxidase conjugate in stabilizer solution	0.045% ProClin 300 0.02% gentamicine sulphate
Substrate	< 0.05% 3,3'5,5'-Tetramethyl-benzidin	
Stop solution	0.3 M Sulfuric acid	
Positive, negative control	inactivated human a-COVID-19 antibodies, 1% goat serum, Tween 20	0.045% ProClin 300 0.09% Na-azide

3.2. Hazardous components and their concentrations

CAS No.	EINECS No.	Ingredient	Percent	Classification (in conc. Form) to
7664-93-9	231-639-5	Sulfuric acid	0.3 M	Acute tox 2, H290

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

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.

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5. Fire-fighting measures

5.1. Extinguishers

Extinguishers indicated: water spray, foam, CO2, 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.

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.

7.3. Specific end-uses

No further relevant information available.

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8.0 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 ³

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 olive-green (samle diluent); red (conjugate); green (positive control); yellow (negative

control); colorless (wash buffer, substrate, stop solution)

Odor: odorless pH-value: <1.0 – 8.0

Melting point / Melting region / boiling point / boiling region / density: not related

Flash point: not applicable

Risk of explosion: no risk of explosion

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.

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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	LD ₅₀	2140 mg/kg	rat

Other health effects

Ingredient	Irritation and corrosion	Sensitization	CMR Effect
Sulfuric acid	no data available	no data available	no data available

12. Ecological information

12.1. Toxicity

Ingredient	Measurand	Value	Species
Sulfuric acid	no data available		

12.2. Persistance and biodegradability

Ingredient	Measurand	Value	Remarks
Sulfuric acid	LD ₅₀	10mg /L/96h	toxic to aquatic organisms due to pH shift

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.

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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).

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.

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15. Regulatory information

This safety data sheet fulfils the requirements of regulation 1907/2006/EG on the registration, evaluation, authorization and restriction of chemicals, (REACH), and the EU regulation 1272/2008/EG on the classification, labeling and packaging of chemicals and mixtures, as well as the regulation (EU) 830/2015 on the production of safety data sheets.

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

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

Product classification to 1272/2008/EG: none

15.2 Chemical safety assessment

A chemical safety assessment has not been performed.

16. Other information

Full text of risk phrases listed in section 3.2.

H290 May be corrosive to metals

H314 Causes severe skin burns and eye damage

H315 Causes skin irritation

Causes serious eye damage H318 H319 Causes serious eye irritation

Abbreviations and acronyms

AGW Arbeitsplatzgrenzwert (workplace limit)

AP BCIP Alkaline Phosphatase

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 Methyllso 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 fur Gefahrstoffe (technical regulations for hazardous chemicals)

TBS Tris buffered saline

USDA US Department of Agriculture

The information given is based on our most current knowledge. It is intended to describe our products in terms of safety requirements, and should be seen by users as a guide. It does not form a guarantee of any specific product features, and does not constitute a legal relationship or state liability for damages which may arise from handling or having contact with this product/ product components.