BioVendor R&D®

MATERIAL SAFETY DATA SHEET

HUMAN GAD AUTOANTIBODY ELISA

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Product name: HUMAN GAD AUTOANTIBODY ELISA
Catalogue number: RGDE/96R

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

Quantitative determination of GAD_{65} autoantibodies in human serum

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína s.r.o.
Karásek 1767/1
621 00 Brno
Czech Republic
Identification number: 63471507

Tel: +420 549 124 185
E-mail: info@biovendor.com

1.4 Emergency telephone number

European Chemicals Agency. National helpdesks contact details
https://echa.europa.eu/support/helpdesks
Links to Poison Centers and Clinical Toxicologists all over the World:
https://www.eapcct.org/index.php?page=links

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Kit Component	Hazard Classification	Hazard Statements
Streptavidin Peroxidase (SA-POD)	Skin Sensitisation, Category 1	H317
Peroxidase Substrate (TMB)	Reproductive Toxicity, Category 1B	H360D

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]:

2.2.1 STREPTAVIDIN PEROXIDASE (SA-POD)

Hazard pictogram	
Signal word:	Warning
Hazard statement(s)	
H317	May cause an allergic skin reaction
Precautionary statement(s)	
P261	Avoid breathing mist, vapours
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352	IF ON SKIN: Wash with plenty of soap and water
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention

P362 + P364	Take off contaminated clothing and wash it before reuse
P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.2.2 PEROXIDASE SUBSTRATE (TMB)

Hazard pictogram	
Signal word:	Danger
Hazard statement(s)	
H360D	May damage the unborn child
Precautionary statement(s)	
P202	Do not handle until all safety precautions have been read and understood
P280	Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313	IF exposed or concerned: Get medical advice/attention
P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.2.3 DILUENT FOR SA-POD

Hazard pictogram	None
Signal word:	Not applicable
Hazard statement(s)	
EUH208	May produce an allergic reaction
Precautionary statement(s)	Not applicable

2.3 Other hazards

All other kit components not listed in section 2.1 and 2.2 do not contain hazardous ingredients in concentrations which meet the criteria for classification according to Regulation (EC) No. 1272/2008. However, ingestion or exposure to large amounts from improper handling can be potentially hazardous.
This kit contains both animal and human proteins and should be treated as a potential biohazard. All animal and human sera have been tested to ensure the absence of infectious agents but all materials should be handled as though capable of transmitting infectious disease and disposed of accordingly.
Peroxidase substrate (TMB) contains material(s) which may be harmful if swallowed. Contains oxidising substance(s) at <0.5%.
ELISA GADAb Kit components ingredients listed in 3.2 have not been identified as having endocrine disrupting properties according to Regulation (EU) 2017/2100 and does not meet the criteria for vPvB and PBT according to Regulation (EC) No. 1907/2006 Annex XIII.
The following precautionary statements should be taken into consideration:
P233, P270, P281, P301 + P330 + P331, P302 + P352, P304 + P340, P305 + P351 + P338 (see section 16 for full text).

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Mixtures

3.1.1 PEROXIDASE SUBSTRATE (TMB)

Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)	Conc. Limits
K-Blue® Advanced TMB Substrate	N/A	N/A	Repr. 1B; H360D	≤100%	≥0.3%
Contains 2-pyrrolidone: CAS No. 616-45-5 EC No. 210-483-1 Concentration: 1 – <10% Classification: Eye Irrit. 2, H319; Repr.1B, H360D **Contains Urea Hydrogen Peroxide:** CAS No. 124-43-6 EC No. 204-701-4 Concentration: 0 – <0.1% Classification: Ox. Sol. 3, H272; Skin Corr. 1B, H314; Eye Dam. 1, H318					

3.1.2 STREPTAVIDIN PEROXIDASE (SA-POD)

Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)	Conc. Limits
StabilZyme® HRP Conjugate Stabilizer	N/A	N/A	Skin Sens. 1; H317	>99%	≥0.1%
Contains 2-methyl-2H-isothiazol-3-one: CAS No. 2682-20-4 EC No. 613-167-00-5 Concentration: 0.0126% Classification: Skin Corr. 1C, H314; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 **Specific Concentration Limits:** C≥0.6% Skin Corr. 1C, H314 **Contains CMIT/MIT: Mixture, 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):** CAS No. 55965-84-9 EC No. 613-167-00-5 Concentration: 0.0024% Classification: Acute Tox. 3 (Oral), H301; Acute Tox. 2 (Dermal), H310; Acute Tox. 3 (Inhalation), H330; Eye Dam. 1, H318; Skin Corr. 1C, H314; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 **Specific Concentration Limits:** C ≥ 0.0015% Skin Sens. 1, H317 C≥0.06% Eye Dam. 1, H318					

3.1.3 DILUENT FOR SA-POD

Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)	Conc. Limits
2-Chloroacetamide	79-07-2	201-174-2	Skin Sens. 1; H317	0.01 ≤ C < 0.1%	≥0.1%
Specific Concentration Limits: C ≥ 0.1% Skin Sens. 1, H317 2-Chloroacetamide concentration is below the cut-off but >10% of specific concentration limit for skin sensitising properties. EUH208 – May produce an allergic reaction.					

GAD_{65}-Biotin, reconstitution buffer for GAD_{65}-Biotin, calibrators and controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

The following kit components contain ingredients which are considered hazardous but are not present in high enough concentrations to be classified under Regulation (EC) No. 1272/2008.

Component(s)	Ingredient	Number	Classification (GHS)	Conc. (v/v)	Conc. Limits (v/v)
Stop Solution	Sulphuric Acid	CAS No. 7664-93-9 EC No. 231-639-5	Met. Corr. 1, Skin Corr. 1A; H290, H314	<5%	Skin Corr. 1A C≥15% Skin Irrit. 2 5%≤C<15% Eye Irrit. 2 5%≤C<15% Met. Corr. 1* C≥0.3%
Diluent for SA-POD	2-Methyl-4-isothiazolin-3- one hydrochloride (MIT)	CAS No. 26172-54-3 EC No. 247-499-3	Acute Tox. 3 (Oral & Dermal), Acute Tox. 2 (inhalation), Skin Corr. 1A, Skin Sens. 1A, Aquatic Chronic 1; H301, H311, H314, H317, H330, H410	<0.1%	Acute Tox. 3 (Oral & Dermal) C≥0.1% Acute Tox. 2 (Inhalation) C≥0.1% Skin Corr 1A C≥5% Skin Irrit. 2 1%≤C<5% Skin Sens. 1A C≥0.1% Aquatic Chronic 1 C≥0.1%
Reconstitution Buffer for GAD_{65}-Biotin Calibrators Controls	Sodium Azide	CAS No. 26628-22-8 EC No. 247-852-1	Acute Tox. 2 (Oral & Inhalation), Acute Tox. 1 (Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; H300, H310, H330, H373, H400, H410, EUH032	<0.1%	Acute Tox. 2 (Oral & Inhalation) C≥0.1% Acute Tox. 1 (Dermal) C≥0.1% STOT RE 2 C≥10% Aquatic Acute 1 C≥0.1% Aquatic Chronic 1 C≥0.1%

*Please note that corrosive to metals does not need to be on the label of Stop Solution as it is exempt under 1.5.2.1.3. of Regulation (EC) No. 1272/2008.
The full text for the hazard statements can be found in section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

After skin contact
Wash off skin thoroughly with water for at least 15 minutes. Remove contaminated clothing. In severe cases or if skin is broken, OBTAIN MEDICAL ATTENTION.

After eye contact
Separate eyelids with fingers and flush eye with copious amounts of water for at least 15 minutes. OBTAIN MEDICAL ATTENTION.

After Inhalation
Remove from exposure, rest and keep warm. If breathing becomes difficult, OBTAIN MEDICAL ATTENTION.

After Ingestion
If patient is conscious, wash out mouth with water and give plenty of water to drink. OBTAIN MEDICAL ATTENTION

4.2 Most important symptoms and effects, both acute and delayed
Not available

4.3 Indication of any immediate medical attention and special treatment needed
Not available

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media
Use water, dry powder or foam as appropriate to supporting fire.

5.2 Special hazards arising from the substance or mixture
May evolve toxic fumes in fire. Hazardous combustion products are not known for kit components but combustion products for the ingredients listed in subsection 3.2 can be found in the following table:

Ingredient	Hazardous combustion product(s)
2-Chloroacetamide	Carbon oxides, nitrogen oxides (NOx) and hydrogen chloride gas
K-Blue® Advanced TMB Substrate	Carbon oxides
MIT	Carbon oxides, nitrogen oxides (NOx), sulphur oxides and hydrogen chloride gas
Sodium Azide	Sodium oxides
StabilZyme® HRP Conjugate Stabilizer	Carbon oxides and nitrogen oxides (NOx)
Sulphuric Acid	Sulphur oxides

5.3 Advice for firefighters
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures
Wear appropriate protective clothing as described in subsection 8.2. Ventilate area and avoid breathing vapours, mist or gas.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

6.3 Methods and material for containment and cleaning up
Wipe up liquid spills with absorbent paper. For solid spills, sweep up without raising dust. Once pick up is complete, wash site with detergent and water. Decontaminate with a suitable disinfectant solution.

6.4 Reference to other sections
See sections 8 and 13.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Material of human origin has been tested and found non-reactive for HIV 1 and 2 and HCV antibodies and HBsAg. All animal sourced material has been obtained from animals certified as healthy and free from disease. However all potentially biohazardous components should be considered as potentially infectious. Level 2 containment should be applied.
Do not eat, drink or smoke in the laboratory. Do not pipette by mouth. Avoid skin and eye contact. Wear appropriate protective clothing as described in subsection 8.2. Avoid the use of needles or other sharp implements. Avoid prolonged or repeated exposure. Wash hands thoroughly after handling. Avoid release into drains; in case of accidental spillage, refer to section 6.

7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed. Store in a dry place in the box supplied at a temperature between +2 and +8°C.

7.3 Specific end use(s)

The BioVendor GADAb Version 2 Kit is intended for professional use only and to be used solely for the purpose as specified in subsection 1.2. Refer to kit instructions for details.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

No occupational exposure limits exist for any kit components. However, exposure limits apply to the following ingredients (see subsection 3.2 for components containing these substances)

Value*	Control Parameters	Basis
Sodium Azide		
TWA	0.1 mg/m3	UK: EH40 Workplace Exposure Limits (WEL) Europe: Commission Directive 2000/39/EC
STEL	0.3 mg/m3	
Sulphuric Acid		
TWA	0.05 mg/m3	UK: EH40 Workplace Exposure Limits (WEL) Europe: Commission Directive 2009/161/EU

StabilZyme® HRP Conjugate Stabilizer	
TRGS 900 Occupational exposure limit value	0.2 mg/m3 inhalable fraction
TRGS 900 Limitation of exposure peaks	0.4 mg/m3 inhalable fraction

*Definitions can be found in section 16

8.2 Exposure controls

Appropriate engineering controls
Good laboratory practice should be followed (see Section 7). Avoid contact with skin or eyes. Wash hands after use.

8.2.1 Personal protective equipment

a) Eye/face protection:

Chemical safety glasses or goggles conforming to appropriate government standards such as EN166 (EU) or NIOSH (US).

b) Skin protection

Hand protection
Chemical resistant gloves to be used in accordance with standard EN374 derived from Regulation (EU) 2016/425. Inspect gloves for damage prior to use and change if any sign of degradation. Proper glove removal technique must be used. Wash hands after use.
The following are suitable as protective gloves:
Glove materials: Nitrile rubber
Glove Thickness: >= 0.4 mm thickness Permeation Time: >= 480 min
This recommendation is advisory only and should be evaluated by the customer for suitability in their specific situation.

c) Respiratory protection:

Local exhaust.

d) Thermal hazards: Not applicable.

Environmental exposure controls
Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Kit component	Appearance	Odour	pH	Solubility
GAD_{65} Coated Wells	Colourless polystyrene microplate	None	N/A	N/A
GAD65-Biotin	White solid	None	N/A	In water
Reconstitution Buffer for GAD-Biotin	Pink liquid	None	~8.3	N/A
Streptavidin Peroxidase (SA-POD)	Pale brown/ yellow liquid	None	N/A	N/A
Diluent for SA-POD	Colourless liquid	None	~7.5	N/A
Peroxidase Substrate (TMB)	Colourless to slight blue liquid	None	N/A	N/A
Stop Solution (0.25M sulphuric acid)	Colourless liquid	May be slightly sulphurous	<1.0	N/A
Concentrated Wash Solution	Colourless liquid	None	~7.6	N/A
Calibrators and Controls	Pale yellow liquid	None	N/A	N/A

There is no information available for the following categories: odour threshold, melting/freezing point, initial boiling point/boiling range, flash point, evaporation rate, flammability (solid, gas), upper/lower flammability or explosive limits, vapour pressure, relative vapour density, relative density, particle characteristics, partition coefficient, autoignition temperature, decomposition temperature, kinematic viscosity, explosive properties or oxidising properties.

9.2 Other information

All liquid components are miscible with water in all proportions.

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Data is not available on the reactivity of individual kit components but is given, where available, on ingredients listed in subsection 3.2.
Sulphuric acid is a strong oxidising agent and has a corrosive effect. There is no data available on the other ingredients.

10.2 Chemical stability

All components of the GADAb ELISA Kit have been found stable for stated shelf life when stored under the recommended conditions

10.3 Possibility of hazardous reactions

No hazardous reactions known for kit components although, hazardous reactions occur for the following ingredients listed in subsection 3.2:

Ingredient	Hazardous Reaction
Sodium Azide	Risk of explosion and/or toxic gas formation exists with heavy metals, bromine, lead, chromyl chloride, dichloromethane, dimethylsulfate, halogenated hydrocarbon, acid, carbon disulphide, sulphuric acid, copper and nitric acid. Generates dangerous gases or fumes with acids and water, leading to the release of hydrazoic acid. Violent reactions possible with nitrates, benzoyl chloride and potassium nitrate.

Sulphuric Acid	Violent reactions possible with: Water, alkali metals, alkali compounds, ammonia, aldehydes, acetonitrile, alkaline earth metals, alkalines, acids, alkaline earth compounds, metals, metal alloys, oxides of phosphorus, phosphorus, hydrides, halogen-halogen compounds, oxyhalogenic compounds, permanganates, nitrates, carbides, combustible substances, organic solvent, acetylidene, nitriles, organic nitro compounds, anilines, peroxides, picrates, nitrides, lithium silicide, iron (III) compounds, bromates, chlorates, amines, perchlorates and hydrogen peroxide.

10.4 Conditions to avoid

Peroxidase substrate (TMB) is light sensitive and therefore the bottle should be kept tightly closed when not in use and stored in a dark place. Peroxidase substrate (TMB) must also be kept away from extreme temperatures.
Proteins, sodium azide and sulphuric acid are heat sensitive and storage or use at the improper temperature may compromise the integrity of the kit.

10.5 Incompatible materials

No data is known for kit components but the following data is known for ingredients listed in subsection 3.2:

Ingredient	Incompatible materials
2-Chloroacetamide	Strong oxidising agents, strong acids, strong bases and strong reducing agents
K-Blue® Advanced TMB Substrate	No data available
MIT	Strong oxidising agents
Sodium Azide	Aluminium and heavy metals
StabilZyme® HRP Conjugate Stabilizer	None known
Sulphuric Acid	Animal and vegetable tissues. Metals. Contact with metals liberates hydrogen gas.

10.6 Hazardous decomposition products

No decomposition products are formed if kit is stored and used under the specified storage and handling conditions.
May evolve toxic fumes in fire. Thermal decomposition products are not known for the kit components but hazardous combustion products of the ingredients listed in subsection 3.2 can be found in subsection 5.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

The kit components have not been directly tested for their toxicological effects, therefore no information is known for these mixtures. The following toxicological data is known for ingredients listed in subsection 3.2:

11.1.1 Acute toxicity

*Definitions can be found in section 16

Ingredient	Measurement*	Value	Species
2-Chloroacetamide	LD50 (Oral)	138 mg/kg	Rat
MIT	LD50 (Oral)	175 mg/kg	Rat
	LC50 (Inhalation)	0.11 mg/L (4h)	Rat
	LD50 (Dermal)	242 mg/kg	Rat
Sodium Azide	LD50 (Oral)	27 mg/kg	Rat
	LC50 (Inhalation)	0.054 – 0.52 mg/L (4h)	Rat
	LD50 (Dermal)	20 mg/kg	Rabbit

Sulphuric Acid	LD50 (Oral)	>2140 mg/kg	Rat
	LC50 (Inhalation)	0.51 mg/L (2h)	Rat

No data available for other ingredients listed in subsection 3.2.

11.1.2 Skin corrosion/irritation

Ingredient	Test/Result
K-Blue® Advanced TMB Substrate	May cause irritation to skin
MIT	Skin (reconstructed human epidermis (RhE)) – Corrosive
Sodium Azide	In vitro study, human skin model test – No skin irritation
Sulphuric Acid	Skin – Rabbit – Result: Extremely corrosive and destructive to tissue

No data available for other ingredients listed in subsection 3.2.

11.1.3 Serious eye damage/irritation

Ingredient	Test/Result
K-Blue® Advanced TMB Substrate	May cause irritation to eyes
MIT MIT	Causes serious eye damage
Sodium Azide	Bovine cornea, exposure time 4 hours – No eye irritation
Sulphuric Acid	Causes serious eye damage – risk of blindness

No data available for other ingredients listed in subsection 3.2.

11.1.4 Respiratory or skin sensitisation

Ingredient	Test/Result
2-Chloroacetamide	Maximisation test, Guinea pig – May cause sensitisation by skin contact
K-Blue® Advanced TMB Substrate	May cause allergic reactions in susceptible people
MIT	Maximisation test, Guinea pig – Result: Positive Local lymph node assay (LLNA) – Result: Positive – Sub category 1A
Sodium Azide	Sensitisation test (dermal), Local lymph node assay (LLNA) – Mouse – Result: Negative
StabilZyme® HRP Conjugate Stabilizer	May cause an allergic skin reaction

No data available for other ingredients listed in subsection 3.2.

11.1.5 Germ cell mutagenicity

Ingredient	Test/Result
2-Chloroacetamide	Hamster, lungs – Negative Mouse, male and female - Negative
K-Blue® Advanced TMB Substrate	No mutagenic effects reported
MIT	Ames test: Salmonella typhimurium – Negative, In vitro mammalian cell gene mutation test: Chinese Hamster Ovary cells – Negative, In vivo micronucleus test: Mouse, male and female – Negative, In vivo unscheduled DNA synthesis assay: Rat, male and female – Negative

Sodium Azide	Chromosome aberration: Chinese hamster ovary cells – Negative Unscheduled DNA Synthesis assay: Chinese hamster lung cells – Negative Sister Chromatid exchange assay: Chinese hamster ovary cells – Negative
Sulphuric Acid	Ames test: Salmonella typhimurium – Negative

No data available for other ingredients listed in subsection 3.2.

11.1.6 Carcinogenicity

Ingredient	Test/Result
2-Chloroacetamide	IARC: No component of this product present at levels ≥0.1% is identified as probable, possible or confirmed human carcinogen by IARC
MIT	
K-Blue® Advanced TMB Substrate	IARC: No components at >0.01% are listed in the ACGIH guide to Occupational Exposure Values, IARC monographs or NTP report on carcinogens and are not listed in the OSHA standard 1910.1003 carcinogens

No data available for other ingredients listed in subsection 3.2.

11.1.7 Reproductive toxicity

Ingredient	Test/Result
2-Chloroacetamide	Suspected human reproductive toxicant
K-Blue® Advanced TMB Substrate	Toxic for reproduction category 1 - May damage fertility or the unborn child.
MIT	Effects on foetal development – Rat – Oral 40 mg/kg bw/day – Result: Negative

No data available for other ingredients listed in subsection 3.2.

11.1.8 STOT-single exposure

Ingredient	Test/Result
K-Blue® Advanced TMB Substrate	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
MIT	Corrosive to respiratory tract

No data available for other ingredients listed in subsection 3.2.

11.1.9 STOT-repeated exposure

Ingredient	Test/Result
K-Blue® Advanced TMB Substrate	No significant hazard - may cause damage to human organs based on animal data.
MIT	Rat – Oral – NOEL 94 mg/kg bw/day – 90 days – Result: Negative Dog – Oral – NOAEL 40.9 mg/kg bw/day – 90 days
Sodium Azide	Oral – may cause damage to organs through prolonged or repeated exposure – Brain

No data available for other ingredients listed in subsection 3.2.

11.1.10 Aspiration hazard

Ingredient	Test/Result
K-Blue® Advanced TMB Substrate	No significant hazard.

No data available for other ingredients listed in subsection 3.2.

11.2 Additional Information

Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Commission Regulations (EU) 2017/2100 and (EU) 2018/605.

Other information

As the kit components have not been tested for their toxicological effects, other hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

SECTION 12 ECOLOGICAL INFORMATION

The kit components have not been tested for their ecological effects, therefore no information is known for these mixtures. The following ecological data is known for ingredients listed in subsection 3.2:

12.1 Toxicity

Ingredients	Toxicity to	Measurement*	Value (inc. exposure time)
2-Chloroacetamide	Fish (Carassius auratus (goldfish))	LC50	19.8 mg/L (96h)
	Daphnia (Daphnia magna (water flea))	EC50	14 mg/L (48h)
MIT	Fish (Oncorhynchus mykiss (rainbow trout))	LC50	4.77 mg/L (96h) (Flow through)
	Daphnia (Daphnia magna (water flea))	EC50	2.33 mg/L (48h) (Static)
	Daphnia (Daphnia magna (water flea))	EC50	0.998 mg/L (48h) (Flow through)
	Algae (Pseudokirchneriella subcapitata (green algae))	ErC50	0.289 mg/L (72h) (Static)
Sodium Azide	Fish (Oncorhynchus mykiss (rainbow trout))	LC50	2.75 mg/L (96h) (Flow through)
	Algae (Psuedokirchneriella subcapita)	ErC50	0.35 mg/L (96h) (Static)
StabilZyme® HRP Conjugate Stabilizer	Fish (Oncorhynchus mykiss (rainbow trout))	LC50	0.19 mg/L
	Daphnia & other aquatic invertebrates (Crassostrea virginica (eastern oyster))	EC50	0.028 mg/L
	Algae	EC50	0.018 mg/L (72h)

Ingredients	Toxicity to	Measurement*	Value (inc. exposure time)
	(Raphidocelis subcapitata (green algae))		
Sulphuric Acid	Daphnia & other aquatic invertebrates (Daphnia magna (water flea))	EC50	>100 mg/L (48h)
	Algae (Desmodesmus subspicatus (green algae))	ErC50	>100 mg/L (72h)

No data available for other ingredients listed in subsection 3.2.

12.2 Persistence and degradability

Test/Result	
2-Chloroacetamide	Biodegradability: aerobic, exposure time 28 days Results: 94% - Readily biodegradable.
MIT	Biodegradability: aerobic, exposure time 28 days Results: 0% - Not readily biodegradable.
StabilZyme® HRP Conjugate Stabilizer	Not rapidly degradable.

No data available for other ingredients listed in subsection 3.2.

12.3 Bioaccumulative potential

Ingredient	Test/Result
MIT	Partition coefficient: n-octanol/water – log Pow: -0.44 (Bioaccumulation is not expected)
StabilZyme® HRP Conjugate Stabilizer	Log Kow: >5 (significant bioaccumulation)

No data available for other ingredients listed in subsection 3.2.

12.4 Mobility in soil

No data available for ingredients listed in subsection 3.2.

12.5 Results of PBT and vPvB assessment

Ingredient	Test/Result
2-Chloroacetamide	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of ≥0.1%.
MIT	
Sodium Azide	
Sulphuric Acid	

12.6 Endocrine disrupting properties

The ingredients listed in subsection 3.2 do not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

12.7 Other adverse effects

The concentrations of ingredients listed in subsection 3.2 are below the acceptable limit for hazardous substances; the ecological risk is minimal. However, it is recommended that reagents do not enter drains in large quantities.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Chemical and biological residues are classified as special waste and as such, are covered by regulations which may vary according to location. Contact your local waste disposal authority for advice or pass to a licensed disposal company. Observe all national and local environmental regulations.
Contaminated packaging should be disposed of using the same routes.

SECTION 14 TRANSPORT INFORMATION

This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).
Transport of this product can be carried out at ambient temperature but in the event of delays store at 2 – 8°C with all reagents contained within the packaging provided.

14.1 UN number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packaging group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

See sections 6 to 8.

SECTION 15 REGULATORY INFORMATION

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

Not applicable.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for the GADAb ELISA Kit by the manufacturer

SECTION 16 OTHER INFORMATION

This SDS has been compiled in accordance with Commission Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2020/878.
All information provided on ingredients listed in subsection 3.2 has been obtained from the appropriate chemical safety data sheets.
Full text of precautionary phrases (listed in subsection 2.3) and hazard statements (listed in subsection 3.2) according to Regulation (EC) No. 1272/2008:
P202: Do not handle until all safety precautions have been read and understood.
P233: Keep container tightly closed.
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear protective gloves/protected clothing/eye protection/face protection.
P281: Use personal protective equipment as required.
P301 + P330 + P331: IF SWALLOWED rinse mouth. Do NOT induce vomiting.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do so. Continue rinsing.
P308 + P313: IF exposed or concerned: Get medical advice/attention.
P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364: Take off contaminated clothing and wash it before reuse.
P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
H272: May intensify fire; oxidiser.
H290: May be corrosive to metals.
H300: Fatal if swallowed.
H301: Toxic if swallowed.
H310: Fatal in contact with skin.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H330: Fatal if inhaled.
H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxic gas.
EUH208: May produce an allergic reaction.

Definitions:

LC50 = The lethal concentration of a substance that kills 50% of the test population within a designated period.
LD50 = Lethal dose for 50% of the test population.
EC50 = The effective concentration of a substance that causes adverse effects in 50% of the test population within a designated period.
ErC50 = The concentration of a substance which results in 50% reduction in growth rate of the test population relative to the control within 72 hours exposure.
STEL = Short term exposure limit 15 minute reference period).
TWA = Time weighted average, long term exposure limit (8 hour reference period).
NOEL = Greatest concentration of a substance that causes no observed alteration to a target organism relative to the control.
NOAEL = Greatest concentration of a substance that causes no observed adverse alteration to a target organism relative to the control.
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