IMMUNOGUIDE ANTIBODY TO CERTOLIZUMAB PEGOL ELISA IG-BB109

SECTION 1-IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product Identifier

PRODUCT NAME	***ImmunoGuide Antibody to Certolizumab Pegol ELISA***
CATALOGUE NUMBER (REF)	***IG-BB109***
INTENDED USE	The ***Antibody to Certolizumab Pegol ELISA*** is an Enzyme-Linked ImmunoSorbent Assay (ELISA) Kit for the quantitative in vitro determination of ***free Antibody to Certolizumab Pegol*** in human serum and plasma.

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

The components of ImmunoGuide-AybayTech ELISA Kits are used as reagents in the in vitro diagnostic determinations of human samples. They are intended for professional use only.

1.3. Details of the supplier of the Safety Data Sheet

Company: AybayTech Biyoteknoloji İmalat San. ve Tic. Ltd. Sti.
Address: Macun Mah. Batı Blv. No: 1/285
06374-Yenimahalle, Ankara
Turkiye
Contact: Tel. +90 312 397 88 05
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E-mail: info@aybaytech.com and info@immunoguide.com
Web site: www.aybaytech.com and www.immunoguide.com

1.4. Emergency Telephone Number

Phone: +90 312 397 88 05 (available during office hours)

SECTION 2-HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

- The components of the ImmunoGuide ELISA kits are not classified as hazardous mixtures according to EC Regulation N° 1272/2008/EC.
- They contain no dangerous substances in concentrations equal to, or exceeding the concentration limits specified in EC Regulation N° 1272/2008/EC.
- The kit components are in small sizes/volumes with a concentration below the acceptable limit for hazardous ingredients.
- The usual precautionary measures are to be adhered to when handling chemicals.
- No toxicological experiments have been performed on the product/kit and its different components. Quantitative data on the toxicity or the ecological effects of the individual mixtures in the kit are not available.
- When used and handled according to specifications, the product does not have any harmful effects to our knowledge.
- Use the product according to GLP and avoid dispersion into the environment to minimize the ecological risk

2.2. Label elements.

These products do not need to be labelled in accordance with EC Regulation N° 1272/2008/EC:

Pictogram : Not applicable.
Signal word : Not applicable.
Hazard Statement(s) : Not applicable.
Precautionary Statement(s) : Not applicable.
Supplemental Hazard Statement(s) : EUH210: Safety Data Sheet available on request

2.3. Other hazards.

*Some ingredients (monoclonal antibodies and albumin) of the ImmunoGuide-AybayTech ELISA Kit mixture are derived from materials of biological origin. No known tests can guarantee that such materials are completely free from infectious agents. Caution should be taken into account while handling the product: treat as potentially infectious.
*Some components, as indicated below, contain sodium azide as a preservative. Sodium azide is toxic and may react with lead and copper plumbing to form explosive compounds. It is harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.
*None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).
Note: This product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

SECTION 3-COMPOSITION AND INFORMATION ON INGREDIENTS

3.1. Substances.

Not applicable:

3.2. Mixtures.

Human source material (recombinant human monoclonal antibody, positive serum or plasma) if used in the preparation of the STANDARDS/CONTROLS/CALIBRATORS has been tested and found non-reactive for HIV-1/2 antibodies, HCV and HbsAg. No known test method can offer complete assurance that Hepatitis B virus, HIV, HCV, or other infectious agents are absent. Handle all biological materials as through capable of transmitting infection.
Purified Albumin protein is used for blocking of “Coated Microtiter Plate” and for that of stabilization purpose in the Standards, Dilution Buffer, Assay Buffer and Conjugate at a concentration less than 1%.
The following substances used in the Kit Components are considered hazardous.
However, at the indicated applied concentrations, it does not warrant hazard labelling.

ELISA KIT COMPONENTS:-COMPOSITION

KIT COMPONENT AND COMPOSITION		
COMPONENT	**LABEL/REF**	**COMPOSITION**
Coated Microtitre Plate	MTP	96-well microtiter plate coated with the specific drug.
Controls/ Calibrators	CNT/ CAL	Buffered protein matrix containing antibody at defined concentrations. **Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).**
Dilution Buffer 5X	DIL BUF 5X	Protein-based aqueous buffered solution. **Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).**
Assay Buffer	ASSAYBUF	Prote in-based aqueous buffered solution. **Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).**
Washing Solution 20X	WASHBUF 20X	20X Concentrated buffered salt solution containing detergent. **Preserved with ProClin™ 300 (CAS: 55965-84-9; N°-CE: 911-828-1) and 5-Bromo-5-nitro-1,3- dioxane (Bronidox L) (CAS: 30007-47-7; N°-CE: 250-001-7).**
Conjugate	ENZCONJ	Horseradish peroxidase (HRP) conjugated Streptavidin stabilized in a buffer solution. **Preserved with ProClin™ 300 (CAS: 55965-84-9; N°-CE: 911-828-1) and 5-Bromo-5-nitro-1,3- dioxane (Bronidox L) (CAS: 30007-47-7; N°-CE: 250-001-7).**
Biotinylated Antibody	BIOTN	Biotinylated Antibody in a stabilized buffer solution. **Preserved with Sodium azide (CAS: 26628-22-8; N°-CE: 247-852-1).**
Chromogen Solution	TMBSUBS	Aqueous solution of TMB (3,3’,5,5’-Tetramethylbenzidin) **(CAS: 54827-17-7; N°-CE: 259-364-6)** and Hydrogen Peroxide **(CAS: 7722-84-1; N°-CE: 231-765-0)**. **Preserved with ProClin™ 300 (CAS: 55965-84-9; N°-CE: 911-828-1).**
Stop Solution	STOP	Aqueous solution of 1 N HCl Hydrochloric Acid **(CAS: 7647-01-0; N°-CE: 231-595-7)**.

KIT COMPONENTS:-HAZARDOUS INGREDIENTS

Hazardous Ingredient	REACH Registration N°	CAS N°	EC N°	Classification + H- and P-Statements	Concentratio
Sodium azide 	01-2119457019- 37-xxxx	26628-22-8	247-852-1	Acute Tox. 2 – H300 Acute Tox. 1 – H310 Acute Tox. 2 – H330 STOT RE 2 – H373 Aquatic Acute 1 – H400 Aquatic Chronic 1 – H410 EUH032 P260, P262, P273, P280 P312, P302+P352 P301+P310 P304+P340	0,09 % (w/v)
ProClin™ 300 (Mixture 3:1 of: • 5-chloro-2-methyl-2H-isothiazol-3-one • 2-methyl-2H-isothiazol-3-one) 	01-2120764691-48-xxxx	55965-84-9	911-828-1	Acute Tox. 2 – H330 Acute Tox. 2 – H310 Acute Tox. 3 – H301 Skin Corr. 1C – H314 Eye Dam. 1 – H318 Skin Sens. 1A – H317 Aquatic Acute 1 – H400 Aquatic Chronic 1 – H410 EUH071 P261, P273, P280, P303+P361+P353 P304+P340 P305+P351+P338, P310	0,025 % (v/v) [~ 0,0008% (w/v)]
5-Bromo-5-nitro-1,3-dioxane (Bronidox L) 	01-2120770242-61-xxxx	30007-47-7	250-001-7	Acute Tox. 4 – H302 Skin Corr. 1A – H314 Eye Dam. 1 – H318 STOT RE 2 – H373 Aquatic Acute 1 – H400 Aquatic Chronic 1 – H410 P273 , P280 , P301+P330+P331, P305+P351+P338	0,21 % (v/v) [~ 0,0225 % (w/v)]
TMB (3,3',5,5'-Tetramethylbenzidin) 	Not listed	54827-17-7	259-364-6	Skin Irrit. 2 – H315 Eye Irrit. 2 – H319 STOT SE 3 – H335 P261, P305+P351+P338	<0,1 % (w/v)
Hydrogen peroxide 	Not listed	7722-84-1	231-765-0	Ox. Liq. 1 – H271 Skin Corr. 1A – H314 Acute Tox. 4 – H302 Acute Tox. 4 – H332 Spec. Conc. Limits: STOT SE 3, C ≥ 35 % Eye Dam. 1, 8 % ≤ C<50 % Eye Irrit. 2, 5 % ≤ C<8 % Ox. Liq. 1, C ≥ 70 % Ox. Liq. 2, 50 % ≤ C < 70 % Skin Corr. 1A, C ≥ 70 % Skin Corr.1B,50%≤C< 70 % Skin Irrit. 2, 35% ≤C< 50 % P220, P280, P305+P351+P338 P310	<1 % (w/v)
Hydrochloric Acid 	017-002-01-xxxx	7647-01-0	231-595-7	Skin Corr. 1B-H314 Spec. Conc. Limits: Eye Irrit. 2; H319:10 %≤C<25% Skin Corr. 1B: C ≥ 25 % Skin Irrit. 2: H315:10 %≤C<25% STOT SE 3; H335: C ≥ 10 % P280 P302+P352 P305+P351+P338	<4 % (w/v)*

*Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1999/45/EC or 1272/2008/EC

See section 16 for the full text of Hazard- and Precautionary Statements.

SECTION 4-FIRST AID MEASURES

4.1. Description of first aid measures.

In general, it is advised to consult a doctor/physician and showing this safety data sheet to the doctor/physician. Consult doctor/physician in case of complaints.

Indications of medical attention:

Eye contact: Flush with running water for at least 15 minutes, ensuring that the eyelids are kept open (separate with fingers). Check for and remove contact lenses if present. Seek medical attention if irritation persists.

Ingestion: If swallowed, seek medical assistance immediately. Wash out mouth with water if victim is conscious. Never give anything by mouth to an unconscious person. Do not try to induce vomiting unless directed to do so by medical personnel.

Inhalation: If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call for medical attention. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash skin with soap and plenty of running water. Remove contaminated clothes. Seek medical attention if irritation or redness of the skin occurs.

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

No data available.

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

No data available.

SECTION 5-FIRST AID MEASURES

5.1. Suitable fire-extinguishing media.

All non-combustible extinguishing media: water spray, carbon dioxide, dry chemical powder or foam.

5.2. Special hazards arising from the substance or mixture.

These product are aqueous liquids and not likely to combust. Large quantities of these products, especially sodium azide, may generate hazardous aerosols in a fire or may decompose by heat to release toxic fumes. Hazardous thermal decomposition products arising from the ingredients may include carbon oxides, nitrogen oxides, sulphur oxides, hydrogen chloride gas.

5.3. Advice for fire-fighters.

If necessary, use protective equipment as a gas-tight suit, eye and skin protection and self-contained breathing apparatus

SECTION 6-ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures.

Clean up spills immediately, avoiding direct contact with the product. Wear appropriate protective clothing (plastic gloves, eye protection and laboratory overall) to prevent skin and eye contact. Avoid breathing vapour or mist and use an air-purifying respirator if aerosols are present. Evacuate the spill area to eliminate unnecessary traffic and to keep unprotected personnel away.

6.2. Environmental precautions.

Contain spills and prevent release to soil, water, drains, sewers or industrial waste water systems.

6.3. Methods and materials for containment and cleaning up.

If feasible, stop any existing leaks. Small spills can be taken up on absorbent material like disposable paper towels. Larger spills may be absorbed in sand, sawdust, diatomaceous earth or universal binders. Collect and store all absorbed material in closed plastic containers until final disposal in accordance with local regulations. After clearing the affected area, wash with plenty of water and detergent.

6.4. Reference to other sections.

See section 8 for personal protection See section 13 for disposal considerations

SECTION 7-HANDLING AND STORAGE

7.1. Handling instructions.

Handle according to good industrial hygiene and safety practices for diagnostic products. Keep containers tightly closed after use. Protect from physical damage. Avoid direct contact with content of the container and prevent or reduce uncontrolled release to the environment. Take care not to splash liquids. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and mind to remove the safety clothing when leaving the working place. Do not eat or drink while handling the product. Do not pipette reagents by mouth. Wash hands and any exposed skin thoroughly after handling.

7.2. Storage instructions.

Store tightly closed in original packaging within temperature limits indicated on the label (at 4-8ºC). Store in a cool, dry and well-ventilated place, away from direct sunlight, heat sources or incompatible materials.

7.3. Specific end use(s).

Use only in accordance with the Instructions For Use (IFU) supplied with the related ImmunoGuide ELISA kit in concern.

SECTION 8-EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control parameters.

The components of ImmunoGuide-AybayTech ELISA Kits do not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.
By using the product according to the requirements, no air pollution is to be expected.

Occupational Exposure Limits.

SUBSTANCE: Sodium Azide (CAS N°. 26628-22-8) -**LISTED**		
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**
Australia	/	0,3 mg/m^3
Canada	/	0,3 mg/m^3
European Union	0,1 mg/m^3	0,3 mg/m^3
New Zealand	/	0,29 mg/m^3
China	/	0,3 mg/m^3
South Korea	/	0,29 mg/m^3
Switzerland	0,2 mg/m^3	0,4 mg/m^3
USA	/	0,3 mg/m^3
United Kingdom	0,1 mg/m^3	0,3 mg/m^3

SUBSTANCE: ProClin™ 300 (CAS N°. 55965-84-9) -**LISTED**		
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**
Australia	0,05 mg/m^3	/
Germany	0,2 mg/m^3	0,4 mg/m^3
Switzerland	0,2 mg/m^3	0,4 mg/m^3

SUBSTANCE: Bromo-5-nitro-1,3-dioxane (Bronidox L) (CAS N°. 30007-47-7) -**NOT LISTED**		
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**
n/a	n/a	n/a

SUBSTANCE: 3,3',5,5'-Tetramethylbenzidin (TMB) (CAS N°. 54827-17-7)-**NOT LISTED**		
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**
n/a	n/a	n/a

SUBSTANCE: Hydrogen peroxide (CAS N°. 7722-84-1)-**LISTED**		
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**
Australia	1,4 mg/m³	/
Austria	1,4 mg/m³	2,8 mg/m³
Belgium	1,4 mg/m³	/
Canada	1,4 mg/m³	/
Denmark	1,4 mg/m³	2,8 mg/m³
Finland	1,4 mg/m³	4,2 mg/m³
France	1,5 mg/m³	/
Germany	0,71 mg/m³	0,71 mg/m³
Ireland	1,5 mg/m³	3,0 mg/m³
China	1,5 mg/m³	/
Singapore	1,4 mg/m³	/
South Korea	1,5 mg/m³	/
Spain	1,4 mg/m³	/
Sweden	1,4 mg/m³	3,0 mg/m³
Switzerland	0,71 mg/m³	0,71 mg/m³
USA	1,4 mg/m³	/
United Kingdom	1,4 mg/m³	2,8 mg/m³

SUBSTANCE: Hydrochloric Acid (CAS N°. 7647-01-0)- **LISTED***		
Country	**OEL Long Term (TWA 8 hours)**	**OEL Short Term (STEL 15 min)**
European Union*	8 mg/m³	15 mg/m³
Great Britain**	2 mg/m³	8 mg/m³

*Source: 2000/39/EC, ** Source: EH40/2005

Other exposure limits.

Users must take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the listed DNELs.

For each component of ELISA Kit (ImmunoGuide AybayTech) such as Coated Microtitre Plate, Standards/Controls/Calibrators, Assay Buffer, Dilution Buffer, Conjugates, TMB and Stop Solution;

DNEL (Derived No Effect Level) : No data available.
PNEC (Predicted No Effect Concentration) : No data available.

For ingredients of the components: Sodium azide (CAS N°. 26628-22-8); ProClin™ 300 (CAS: 55965-84-9); 5-Bromo-5-nitro-1,3- dioxane (Bronidox L) (CAS: 30007-47-7); TMB (CAS: 54827-17-7); Hydrogen Peroxide (CAS: 7722-84-1); Hydrochloric Acid (CAS: 7647-01-0).

DNEL (Derived no effect level)					
Substance	**Parameter**	**Exposure**	**Value**	**Population**	**Effects**
Sodium azide	DNEL	Long term, Inhalation	0,164 mg/m³	Workers	Systemic
Sodium azide	DNEL	Long term, Inhalation	46,7 µg/kg bw/day	Workers	Systemic
ProClin™ 300	DNEL	No data	No data	No data	No data
5-Bromo-5-nitro-1,3-dioxane	DNEL	Long term, inhalation	0,0274 mg/m³	Workers	Systemic
TMB	DNEL	No data	No data	No data	No data
Hydrogen Peroxide	DNEL	Long term, inhalation	1,4 mg/m³	Workers	Local
Hydrogen Peroxide	DNEL	Acute term, inhalation	3,0 mg/m³	Workers	Local
Hydrochloric Acid	DNEL	Long term, inhalation	8 mg/m³	Workers	Local
Hydrochloric Acid	DNEL	Acute term, inhalation	15 mg/m³	Workers	Local

PNEC (Predicted No Effect Concentration)			
Substance	**Parameter**	**Ecosystem**	**Concentration**
Sodium azide	PNEC	Freshwater	0,35 µg/L
Sodium azide	PNEC	Sewage treatment plant (STP)	30 µg/L
Sodium azide	PNEC	Freshwater sediment	16,7 µg/kg
Sodium azide	PNEC	Marine sediment	0,72 µg/kg
ProClin™ 300	PNEC	No data	No data
5-Bromo-5-nitro-1,3-dioxane	PNEC	Australian river	7.3 µg/L
5-Bromo-5-nitro-1,3-dioxane	PNEC	Marine water	8.8 µg/L
TMB	PNEC	No data	No data
Hydrogen Peroxide	PNEC	Fresh water	0,0126 mg/L
Hydrogen Peroxide	PNEC	Marine water	0,0126 mg/L
Hydrogen Peroxide	PNEC	Fresh water sediment	0.474 mg/kg
Hydrogen Peroxide	PNEC	Marine sediment	0,047 mg/kg
Hydrogen Peroxide	PNEC	Soil	0,0023 mg/kg
Hydrogen Peroxide	PNEC	Sewage treatment plant	10 mg/L
Hydrochloric Acid	PNEC	Freshwater	0.036 mgL
Hydrochloric Acid	PNEC	Marine water	0.036 mgL
Hydrochloric Acid	PNEC	Soil (Agriculture)	0.036 mgL dw

8.2. Exposure controls.

Appropriate engineering controls.

The usual precautionary measures are to adhered to when handling chemicals. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below the recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment.

Hygiene measures:	Wash hands after handling chemical products, before eating, at the end of each working period. Wash contaminated clothing before reuse. Provide eyewash equipment and safety showers close to the working place.
Eye/face protection:	Wear safety glasses with side-shields or goggles conforming to EN 166.
Skin protection:	**Hand protection:** Wear disposable, chemical resistant, protective gloves (neoprene, nitrile, latex) conforming to EN 374. Mean Breakthrough Time > 480 min. **Body protection:** Wear a suitable laboratory coat or protective garment according to the task being performed and the risks involved. Change contaminated clothing immediately.
Respiratory protection:	Not normally required in normal handling conditions. Provide appropriate general room ventilation. Avoid splashing or generation of sprays to minimize risk of aerosol formation. Avoid direct contact with respiratory system. If permissible exposure limit levels are exceeded, provide an air-purifying respirator and filter type complying with an approved standard (EN 136, EN 140, EN 14387).

Environmental exposure controls.

Every waste disposal must be in compliance with national and local regulations. Avoid release into soil, water supplies or sewage system

SECTION 9-PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties.

STANDARDS/CONTROLS/CALIBRATORS	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid or lyophilized (has no influence to the properties of the mixture). Diverse (has no influence to the properties of the mixture
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	7,2 – 7,5
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	The ingredient sodium azide may form explosive compounds with metals including copper, lead, mercury, silver and brass.
Oxidizing properties:	Not fire-propagating.

DILUTION BUFFER 5X (DIL BUF 5X)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. It contains an inert dye, making it orange in colour.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	7,2 – 7,5
Melting point/freezing point:	No data available.
Boiling point:	100^{o}C.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	The ingredient sodium azide may form explosive compounds with metals including copper, lead, mercury, silver and brass.
Oxidizing properties:	Not fire-propagating.

ASSAY BUFFER (ASSAYBUF)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. It contains an inert dye, making it blue in colour.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	7,2 – 7,5
Melting point/freezing point:	No data available.
Boiling point:	100ºC.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	The ingredient sodium azide may form explosive compounds with metals including copper, lead, mercury, silver and brass.
Oxidizing properties:	Not fire-propagating.

WASHING SOLUTION 20X (WASHBUF 20X)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. Clear-colourless.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	7,0 – 7,4
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	Product is not explosive.
Oxidizing properties:	Not fire-propagating.

BIOTINYLATED ANTIBODY (BIOTN)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. It contains an inert dye, making it green in colour.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	7,2 – 7,5
Melting point/freezing point:	No data available.
Boiling point:	100ºC.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	The ingredient sodium azide may form explosive compounds with metals including copper, lead, mercury, silver and brass.
Oxidizing properties:	Not fire-propagating.

CONJUGATE (ENZCONJ)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. It contains an inert dye, making it red in colour.
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	5,5 – 6,5
Melting point/freezing point:	No data available.
Boiling point:	100ºC.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	Product is not explosive.
Oxidizing properties:	Not an Oxidizer.

CHROMOGEN SOLUTION (TMBSUBS)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. Clear to light yellow
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	3,5 – 4,5
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	Product is not explosive.
Oxidizing properties:	Not an Oxidizer.

STOP SOLUTION (STOP)	
Physical appearance & The physical state (solid, liquid, gas): Color:	Liquid. Clear-Colourless
Odour:	Odourless.
Odour threshold:	No data available.
pH value:	1
Melting point/freezing point:	No data available.
Boiling point:	No data available.
Flash point:	Not considered to be a fire hazard.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	Not measured.
Solubility:	Miscible with water.
Partition coefficient:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

9.2. Other information.

No further information available.

SECTION 10-STABILITY AND REACTIVITY

10.1. Reactivity
No test data related to reactivity available for this product.

10.2. Chemical stability
Stable under normal temperatures stated on label and pressures. Stable until expiry date stated on label when stored as indicated.

10.3. Possibility of hazardous reactions
By using the product according to the requirements, no hazardous reactions are to be expected.

10.4. Conditions to avoid
Do not expose to elevated temperatures or direct sunlight. Do not boil or heat to dryness. Do not freeze. Avoid keeping containers opened for prolonged periods.

10.5. Incompatible materials
Plumbing metals (lead, copper) and many other metals including mercury and silver may react explosively with sodium azide. Acids may react with sodium azide and form very toxic hydrogen azide. Avoid contact with strong oxidizing agents, acids, peroxides, acid chlorides.
For Chromogenic Substrate (TMB): Avoid contact with strong oxidizing agents, metals and metal salts; possible destruction of the quality of the product. Incompatible with acids, alkalis and reducing agents.
For Stopping Solution: Avoid contact with bases, halides, organic materials, cyanides, chlorates, carbides, metals and metal salts, phosphorus.

10.6. Hazardous decomposition products
Thermal decomposition may produce small quantities of nitrogen oxides, sodium oxide fumes and oxides of carbon.

SECTION 11-TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008

There are no toxicological data available for the components of ImmunoGuide-AybayTech ELISA Kits as a mixture.
However, one can consider the effects of exposure to the individual hazardous components of the mixture to assess toxicological effects resulting from exposure to the mixture.

Following toxicological information is available for **Sodium Azide:**

Acute toxicity

Acute toxicity data for Sodium azide	
LD50,oral, mouse	27,0 mg/kg
LD50,oral, rat	27,0 mg/kg
LD50,inhalation, mouse	32,4 mg/m^3
LD50,inhlation, rat	37,0 mg/m^3
LD50,skin, rat	50,0 mg/kg
LD50,skin, rabbit	20,0 mg/kg

Corrosion/Irritation:

Eye contact: Mild eye irritation.
Ingestion: Harmful for digestive system, toxic neurological effects.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness, possible absorption of sodium azide through skin, causing systemic toxicity.

Sensitisation:	No information available.
Germ cell mutagenicity:	No data available on humans.
Carcinogenicity:	Sodium azide is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH
Mutagenicity:	Sodium azide is mutagenic in vitro for bacteria and mammalian cells, no data available on humans.
Reproductive toxigenicity:	No data available on humans.
Specific target organ toxicity: (single exposure)	Respiratory system, Central Nervous System (CNS).
Specific target organ toxicity: (repeated exposure)	Cardiovascular system, respiratory and digestive organs. Liver, kidney, heart, spleen.
Aspiration hazard:	No information available.

Signs and symptoms of exposure:
Symptoms of acute ingestion of sodium azide may include sweating, headache, increased puls rate, decreased blood pressure, blurred vision and faintness. Oedema of brain and lungs, abdominal organ congestion and diffuse redness of mucous membranes are also reported in severe cases of intoxication. Inhalation of sodium azide may cause acute hypotension, nausea, vomiting and weakness. Dermal exposure in general only causes mild skin irritation. In extreme cases, skin burns or blisters have been reported.

Following toxicological information is available for **ProClin™ 300:**

Acute toxicity

Acute toxicity data for ProClin™ 300	
LD50,oral, rat	852,0 mg/kg
LD50,skin, rabbit	2800,0 mg/kg

Corrosion/Irritation:
Eye contact: Corrosive. Causes eye burns.
Ingestion: May be harmful if swallowed. Causes burns.
Inhalation: May be harmful if inhaled. Destructive to mucous membranes and upper respiratory tract. Causes respiratory tract irritation.
Skin contact: May be harmful if absorbed through skin. Causes skin burns.

Sensitisation:	May cause allergic skin reactions. May provoke asthmatic response in persons with asthma who are sensitive to airway irritants.
Germ cell mutagenicity:	Data conclusive but not sufficient for classification.
Carcinogenicity:	Data conclusive but not sufficient for classification.
Reproductive toxigenicity:	Data conclusive but not sufficient for classification.
Specific target organ toxicity: (single exposure)	Data conclusive but not sufficient for classification.
Specific target organ toxicity: (repeated exposure)	Data conclusive but not sufficient for classification.
Aspiration hazard:	Data conclusive but not sufficient for classification.

Signs and symptoms of exposure:
Burning sensation. Cough and wheezing. Shortness of breath, spasm. Oedema and inflammation of larynx, pulmonary oedema, laryngitis and pulmonitis.

Following toxicological information is available for **Bronidox L:**

Acute toxicity

Acute toxicity data for Bronidox L	
LD50,oral, mouse	550,0 mg/kg
LD50,oral, rat	455,0 mg/kg
LD50,intraperitoneal, rat	31,0 mg/kg

Corrosion/Irritation:
Eye contact: Undiluted substance causes serious eye damage. SCL = 0,1 %.
Ingestion: Possibly toxic with neurological and behavioural effects (tremor, convulsions, excitement).
Inhalation: May be harmful if inhaled. Causes respiratory tract and mucous membrane irritation.
Skin contact: Undiluted substance causes severe burns. SCL = 0,1 %

Sensitisation:	Respiratory sensitisation: data lacking. Skin sensitisation: data conclusive but not sufficient for classification.
Germ cell mutagenicity:	Data inconclusive.
Carcinogenicity:	Data lacking.
Reproductive toxigenicity:	Data conclusive but not sufficient for classification.
Specific target organ toxicity: (single exposure)	Data conclusive but not sufficient for classification.
Specific target organ toxicity: (repeated exposure)	May cause damage to organs through prolonged or repeated exposure. Affected organs: stomach, liver, hart.
Aspiration hazard:	No data available.

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **TMB:**

Acute toxicity

No Data Available

Corrosion/Irritation:
Eye contact: Causes serious eye irritation.
Ingestion: Harmful if swallowed.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation or redness.

Sensitisation:	No data available on humans. Genotoxicity in vitro - mouse - lymphocyte Mutation in mammalian somatic cells.
Germ cell mutagenicity:	TMB is not listed as carcinogenic by IARC at a concentration of < 0,1 % (w/v) and not classifiable as carcinogenic by ACGIH.
Carcinogenicity:	No data available on humans.
Reproductive toxigenicity:	No data available on humans.
Specific target organ toxicity: (single exposure)	No data available.
Specific target organ toxicity: (repeated exposure)	No data available.
Aspiration hazard:	No data available.

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Hydrogen peroxide:**

Acute toxicity

Acute toxicity data for Hydrogen peroxide	
LD5O,skin, rabbit	2000,0 mg/kg
LD5O,oral, rabbit	693,7-1270,0 mg/kg

Corrosion/Irritation:
Eye contact: Causes serious eye irritation. Conjunctivitis.
Ingestion: Irritation of mucous membranes in mouth, pharynx, oesophagus, gastrointestinal tract.
Inhalation: Irritation of respiratory tract and mucous membranes.
Skin contact: Skin irritation after prolonged exposure. May cause skin burns

Germ cell mutagenicity:	No data available on humans.
Carcinogenicity:	Hydrogen peroxide is not listed as carcinogenic.
Mutagenicity	No data available on humans.
Reproductive toxigenicity:	No data available on humans.
Specific target organ toxicity: (single exposure)	Not classified as specific target organ toxicant.
Specific target organ toxicity: (repeated exposure)	Not classified as specific target organ toxicant.
Aspiration hazard:	No data available

Signs and symptoms of exposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Following toxicological information is available for **Hydrochloric acid:**

Acute Toxicity – Oral: Based on available data, the classification criteria are not met.
Acute Toxicity – Dermal: Based on available data, the classification criteria are not met.
Acute Toxicity – Inhalation: Based on available data, the classification criteria are not met.

Acute toxicity

Acute toxicity data for Hydrogen peroxide	
LD5O,oral, rat	238 – 277 mg/kg
LD5O,dermal, rabbit	>5010 mg/kg
LC5O,inhalation, rat	1.68 mg/L (1h)

Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Sensitization:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Mutagenicity	Based on available data, the classification criteria are not met.
Reproductive toxigenicity:	Based on available data, the classification criteria are not met.
Specific target organ toxicity: (single exposure)	Based on available data, the classification criteria are not met.
Specific target organ toxicity: (repeated exposure)	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.

Signs and symptoms of exposure:
Eye contact: Causes severe eye irritation.
Ingestion: Harmful if swallowed.
Inhalation: Destructive to tissues of upper respiratory tract and mucous membranes.
Skin contact: Causes skin burns.

11.2. Endocrine disrupting properties
None of the ingredients are listed

11.3. Additional toxicological information
Quantitative data on the toxicity of the product are not available. When used and handled according to specifications, the product does not have any harmful effects to our knowledge.

SECTION 12-ECOLOGICAL INFORMATION

Quantitative data about the ecological effects of components of ELISA Kit as mixtures are not available. Use the product according to GLP and avoid dispersion into the environment.

12.1. Toxicity

Available ecological toxicity information for the ingredients used in the formulation of the ELISA Kit components.

Eco-toxicity data for Sodium Azide (CAS: 26628-22-8)		
Fish Toxicity:	LC50 Bluegill sunfish	0,68 mg/L/96 hr
Invertebrate (Crustacean) Toxicity:	LC50 Water flea	9,0 mg/L/48 hr
Invertebrate (Crustacean) Toxicity:	EC50 Water flea	4,2 mg/L/48 hr
Algae Toxicity:	EC50 Algae	0,348 mg/L/96 hr

Eco-toxicity data for ProClin™ 300 (CAS: 55965-84-9)		
Fish Toxicity:	LC50 Rainbow trout	0,19 mg/L/96 hr
Fish Toxicity:	LC50 Bass	0,28 mg/L/96 hr
Invertebrate (Crustacean) Toxicity:	EC50 Water flea	0,16 mg/L/48 hr
Algae Toxicity:	EC50 Marine Algae	0,003 mg/L/48 hr

Eco-toxicity data for Bronidox L (CAS: 30007-47-7)		
Fish Toxicity:	LC50 Fish	> 1–10 mg/L/96 hr

Eco-toxicity data for TMB (CAS: 54827-17-7)		
No data available		

Eco-toxicity data for Hydrogen Peroxide (CAS: 7722-84-1)		
Fish Toxicity:	LC50 Fish	22,0 – 26,7 mg/L/96 hr
Invertebrate Toxicity:	EC50 Water flea	7,7 mg/L/24 hr
Algae Toxicity:	IC50 Fresh water algae	2,5 mg/L/72 hr

Eco-toxicity data for Hydrochloric Acid (CAS: 7647-01-0)		
Fish Toxicity	LC50 Fresh water fish	282 mg/L/96 h
Invertebrate Toxicity:	EC50 Water Flea	56mg/L/ 72h

12.2. Persistence and degradability
No information available.

12.3. Bioaccumulative potential
No information available.

12.4. Mobility in soil
No information available.

12.5. Results of PBT and vPvB assessment
None of the components are listed as PBT (Persistent/Bio-accumulative/Toxic) or vPvB (very Persistent/very Bio-accumulative).

12.6. Endocrine disrupting properties
No endocrine disrupting properties for the environment identified based on the information derived from assessment criteria laid down in Regulations N° 2017/2100/EU and N° 2018/605/EU.

12.7. Other adverse effects
Sodium azide, ProClin® 300 are very toxic and Bronidox L is toxic to aquatic organisms. They may cause long-term adverse effects in the aquatic environment. Do not allow products to come in contact with surface waters. Do not discharge products into sewers or waterways.

SECTION 13-DISPOSAL CONSIDERATION

13.1. Waste treatment methods

Product
Every waste disposal must be in compliance with national and local regulations. Observe all Federal, Regional and Local legislation concerning health and pollution. Dispose of residual products and their containers and residues from tests using these reagents as hazardous waste. Collect in medical waste containers according to rules for the disposal of clinical specimens. These waste containers are to be collected and transported by a certified Disposal Company and incinerated in a regulated facility.

Packaging
Packaging material, if not contaminated, can be treated as normal household waste or might be recycled. Contaminated packages have to be treated in the same way as described under the section of product just above.

SECTION 14-TRANSPORT INFORMATION

These products contain no hazardous materials subjected to Transport Regulations and is not covered by international regulations on the transport of dangerous goods (ADR/RID, IATA/ICAO, IMO/IMDG, US DOT).

Land transport (road/rail) ADR/RID:	No limitations/not classified
Air transport (air) IATA/ ICAO:	No limitations/not classified
Maritime transport (sea) IMO/IMDG:	No limitations/not classified
US Department of transportation (US DOT):	No limitations/not classified

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

14.1. UN number or ID number
ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.2. UN proper shipping name
ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.3. Transport hazard class(es)
ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.4. Packing group
ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.5. Environmental hazards
ADR/RID, IATA/ICAO, IMO/IMDG, US DOT: Not applicable

14.6. Special precautions for user
No data available.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

SECTION 15-REGULATORY INFORMATION

This product has been classified and labeled according to the European regulation (EC) N° 1272/2008 on dangerous substances and mixtures.

15.1. Safety, health and environmental regulations/Legislation specific for the substance or mixture
This Safety Data Sheet complies with the requirements of Regulation N° 1907/2006/EC and Regulation N° 2020/878/EU amending Annex II to Regulation N° 1907/2006.

Labelling according to EU guidelines:

The information supplied on the labels and Instructions For Use of these products are in accordance with EU Regulation N° 1272/2008/EU, amended by EU Regulations according to updates from ATPs (Adaptation to the Technical Progress) of the CLP Regulation and with Annex I of Directive 98/79/EC.

Other EU Regulations:

This product is NOT subject to Regulation N° 1005/2009/EC (no ozone depleting agent) and to Regulation N° 850/2004/EC (not a persistent organic pollutant).

15.2. Chemical safety assessment
No data available. A chemical safety assessment has not been carried out for this product.

SECTION 16-OTHER INFORMATION

Meaning of Hazard symbols, Hazard and Precautionary Statements used:

Hazard symbol & meaning	
	GHS03: Danger or Warning - Oxidising
	GHS05: Danger or Warning - Corrosive
	GHS06: Danger - Toxic
	GHS07: Warning - Irritant
	GHS08: Danger or Warning – Systemic health hazards
	GHS09: Warning - Environment

Hazard Statements & meaning	
H271	May cause fire or explosion; strong oxidizer.
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility of the unborn child.
H373	Causes 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.
EUH071	Corrosive to the respiratory tract.

Precautionary Statements & meaning	
P220	Keep away from clothing and other combustible materials.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P262	Do not get in eyes, on skin, or on clothing.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…
P310	Immediately call a POISON CENTER/doctor/…
P312	Call a POISON CENTER/doctor/… if you feel unwell.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor….
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302+P352	IF ON SKIN: Wash with plenty of water/…
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep 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. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.

Abbreviations used in the text:

ACGIH :	American Conference of Governmental Industrial Hygienists.
ADR :	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS :	Chemical Abstracts Service.
CLP :	Classification, Labelling, Packaging.
GHS :	Globally Harmonized System of Classification and Labelling of Chemicals.
IARC :	International Agency for Research on Cancer.
IATA :	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by IATA.
ICAO :	International Civil Aviation Organization.
IMO :	International Maritime Organization
IMDG :	International Maritime Code for Dangerous Goods
LC50 :	Lethal concentration which kills 50 % of a sample population of a specific test animal following a specified exposure time.
LD50 :	Lethal dose which kills 50 % of a sample of a specific test animal following a specified exposure time.
EC50 :	Effect concentration whereby 50 % of a sample of test organisms show an effective response following a specified exposure time.
OEL :	Occupational Exposure Limit (European threshold limit value).
REACH :	Registration, Evaluation, Authorization and Restriction of Chemicals.
RID :	Regulation concerning the International Transport of Dangerous Goods by Rail.
STEL :	Short Term Exposure Limit.
STOT RE :	Specific Target Organ Toxicity – Repeated Exposure.
TWA :	Time Weighted Average 8 hours day
ACGIH :	American Conference of Governmental Industrial Hygienists.
ADR :	European Agreement concerning the International Carriage of Dangerous Goods by Road.
U.S. DOT :	US Department of transportation

Revisions since previous version
Adaptations according to Regulation N° 2020/878/EU.

Sections 1, 3, 8, 12, 14, 15, 16.

Notice to the product user:

To the best of our knowledge, the information contained in this safety data sheet is believed to be correct at the time of preparation. However, because the physical, chemical and toxicological properties of these products have not been fully investigated, they may present unknown hazards and should be used with caution.

The manufacturer makes no warranty with respect to the accuracy or completeness of this information and assumes no liability whatsoever for any loss or injury which may result from the use of the product. Final determination of suitability of any material is the sole responsibility of the user.