1) Identification:

Product

Product name: ANTISURASE B-96 II (TMB)

Product code: 4SBE6 (96 Tests) **Restriction on use:** In-Vitro Diagnostics for professional use only

Intended use: ANTISURASE B-96 II (TMB) kit is an enzyme immunoassay diagnostic kit for in-vitro quantitative detection of antibody to hepatitis B surface antigen (HBsAg) in human serum or plasma (heparin, citrate or EDTA).

Product components:

#	Components	4SBE6 (96 tests)
1	HBsAg Plate	1 plates
2	HBsAg・Peroxidase Solution	1 bottle, 8 mL
3	Zero Control	1 bottle, 10 mL
4	Anti-HBs Standard 1000 mIU/ml	1 bottle, 2.5 mL
5	Anti-HBs Standard 400 mIU/ml	1 bottle, 2.5 mL
6	Anti-HBs Standard 100 mIU/ml	1 bottle, 2.5 mL
7	Anti-HBs Standard 50 mIU/ml	1 bottle, 2.5 mL
8	Anti-HBs Standard 25 mIU/ml	1 bottle, 2.5 mL
9	Anti-HBs Standard 10 mIU/ml	1 bottle, 2.5 mL
10	TMB Substrate Solution A	1 bottle, 12 mL
11	TMB Substrate Solution B	1 bottle, 12 mL
12	Conc. Washing Solution D (20X)	1 bottle, 58 mL
13	1 N H_2SO_4	1 bottle, 12 mL

Manufacturer details

Company: GENERAL BIOLOGICALS CORP.

Address of the company:

#6, INNOVATION FIRST ROAD, HSINCHU SCIENCE PARK, BAOSHAN TOWNSHIP, HSINCHU COUNTY 30076, TAIWAN, R.O.C.

Telephone Number for emergency of the company: 886-3-5779221 ext. 254

Fax number of the company: 886-3-5779227

E mail of the company: Sales.group@gbc.com.tw

2) Hazards Identification:

This kit must be operated by qualified personnel trained in laboratory procedures and familiar with its potential hazards. The warnings during operation are given in the instruction for use.

2.1) Classification of the mixture

Components	Classification
Component #10 **TMB Substrate Solution A**	Reproductive toxicity [Category 1B]
	Specific target organ toxicity - Single exposure [Category 2] Visual system, Central nervous system
	Specific target organ toxicity - Repeated exposure [Category 2] Visual system, Central nervous system
	Flammable liquid [Category 3]
Component #13 **1 N Sulfuric Acid**	Corrosive to metals [Category 1]
	Skin corrosion [Category 1A]

The other kit components are not classified as hazardous mixture or substance according to GHS / CLP.

2.2) Label elements

Component #10 **TMB Substrate Solution A**	 **Danger**  **Warning**
Label Hazard Statement:	**H226: Flammable liquid and vapour** **H340: May cause genetic defects** **H371: May cause damage to organs** **H373: May cause damage to organs**
Supplemental Hazard – Statement:	None Specified
Precautionary Statement – Prevention:	P202: Do not handle until all safety precautions have been read and understood. P210: Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P280: Wear protective gloves/protective clothing/eye protection/ face protection.
Precautionary Statement – Response:	P308 + P313: IF exposed or concerned: Get medical advice / attention.
Precautionary Statement – Storage:	P405: Store locked up.
Precautionary Statement – Disposal:	P501: This material and its container must be disposed of as hazardous waste.

Component #13 **1N Sulfuric Acid**	 **Danger**
Label Hazard Statement:	**H290: May be corrosive to metals.** **H314: Causes severe skin burns and eye damage.**
Supplemental Hazard – Statement:	None Specified
Precautionary Statement – Prevention:	P260: Do not breathe mist / vapours / spray. P280: Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement – Response:	P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. Continue rinsing. P309 + P313: If exposed or if you feel unwell: get medical advice/attention.
Precautionary Statement – Storage:	P405: Store locked up.
Precautionary Statement – Disposal:	P501: This material and its container must be disposed of as hazardous waste.

2.3) Other hazards

Component #1 HBsAg Plate	**Component #5** Anti-HBs Standard 400 mIU/ml	
Component #2 HBsAg・Peroxidase Solution	**Component #6** Anti-HBs Standard 100 mIU/ml	
Component #3 Zero Control	**Component #7** Anti-HBs Standard 50 mIU/ml	
Component #4 Anti-HBs Standard 1000 mIU/ml	**Component #8** Anti-HBs Standard 25 mIU/ml	
	Component #9 Anti-HBs Standard 10 mIU/ml	

Biological ingredient _ Potential Biohazard

Human/ animal sourced mixture in these components, handle as potentially infectious. Patient specimens analyzed with the kit represent an unknown, heightened biohazard, too.

3) Composition/information on ingredients:

Component	Hazardous Ingredient	CAS No.	Classification (100%)	Con. (W/W)
#2 HBsAg・ Peroxidase Solution	Human/Animal sourced mixture	N/A	N/A	100 %
	Gentamycin	1405-41-0	Respiratory sensitisation (Category 1), H334 Skin sensitisation (Category 1), H317	<0.01 %
	Thimerosal	54-64-8	Specific target organ toxicity - repeated exposure (Category 2), H373 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Acute toxicity, Oral (Category 2), H300 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.01 %
#3 Zero Control	Human/Animal sourced mixture	N/A	N/A	100 %
	Gentamycin	1405-41-0	Respiratory sensitisation (Category 1), H334 Skin sensitisation (Category 1), H317	<0.01 %
	Thimerosal	54-64-8	Specific target organ toxicity - repeated exposure (Category 2), H373 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Acute toxicity, Oral (Category 2), H300 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.01 %
#4~#9 Standards	Human/Animal sourced mixture	N/A	N/A	100 %
	Gentamycin	1405-41-0	Respiratory sensitisation (Category 1), H334 Skin sensitisation (Category 1), H317	<0.01 %

	Thimerosal	54-64-8	Specific target organ toxicity - repeated exposure (Category 2), H373 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Acute toxicity, Oral (Category 2), H300 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.01 %
#10 TMB Substrate Solution A	3,3',5,5'-tetramethyl Benzidine.	54827-17-7	Skin irritation (Category 2), H315 Eye irritation (Category 2), H319 Specific target organ toxicity - single exposure (Category 3), H335	~0.04 %
	Methanol	67-56-1	Flammable liquids (Category 2), H225 Acute toxicity (Oral) (Category 5), H303 Serious eye damage/eye irritation (Category 2A), H319 Reproductive toxicity (Category 1B), H340 Specific target organ toxicity - Single exposure (Category 1) Visual system, Central nervous system, H370 Specific target organ toxicity- Single exposure (Category 3) Respiratory tract irritation, Narcotic effects, H335/H336 Specific target organ toxicity- Repeated exposure (Category 1) Visual system, Central nervous system H372	~4 %
#11 TMB Substrate Solution B	Urea Hydrogen Peroxide	124-43-6	Oxidizing solids (Category 3), H272 Skin corrosion (Category 1B), H314	~0.05 %
	Gentamycin	1405-41-0	Respiratory sensitisation (Category 1), H334 Skin sensitisation (Category 1), H317	< 0.1 %
#13 1 N Sulfuric Acid	Sulfuric Acid	7664-93-9	Corrosive to metals (Category 1), H290 Skin corrosion (Category 1A), H314	4.94 %

4) First aid Measures:

4.1) Description of first aid measures

Inhalation	Remove to fresh air. Seek medical advice.
Swallowed	Rinse out mouth thoroughly with water. Seek medical advice.
Eye contact	Flush with copious amounts of water. Seek medical advice.
Skin contact	Flush thoroughly with water. Seek medical advice.
Protection of first-aids	Wearing of protective gloves and avoiding the generation of aerosols.

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

5) Fire Fighting Measures:

5.1) Extinguishing media: CO_2, powder or water spray.

Fight larger fires with water spray or alcohol resistant foam.

5.2) Hazardous combustion products

#	Components	Specific Hazards
1	HBsAg Plate	CO.
2	HBsAg・Peroxidase Solution	CO, NO_x, SO_x, Hg.
3	Zero Control	CO, NO_x, SO_x, N_2.
4-9	Standards	CO, NO_x, SO_x, N_2.
10	TMB Substrate Solution A	CO, NO_x, SO_x.
11	TMB Substrate Solution B	CO
12	Conc. Washing Solution D (20X)	CO
13	1 N Sulfuric Acid	SO_x.

5.3) Advice for firefighters

Wear self-contained breathing apparatus if necessary.

6) Accidental Release Measures:

6.1) Personal Precautions

Wear protective gloves, lab coat and avoid the generation of aerosols. Keep unprotected persons away and ensure adequate ventilation.

6.2) Environmental Precautions

Treat (inactivate) as biological hazardous contamination.

6.3) Methods for Cleaning Up

#	Components	Methods for Cleaning Up
2	HBsAg・Peroxidase Solution	Inactivate with Sodium Hypochlorite Solution prior to clean with plenty of water.
3	Zero Control	
	Zero Control	
4-9	Standards	
10	TMB Substrate Solution A	Clean with plenty of water.
11	TMB Substrate Solution B	
12	Conc. Washing Solution D (20X)	
13	1 N Sulfuric Acid	

7) Handling and Storage:

7.1) Handling:

This kit must be operated by qualified personnel trained in laboratory procedures and familiar with its potential hazards. The warnings during operation are given in the instruction for use. Handled as biohazards and wear protective gloves and lab coat.

Keep TMB Substrate Solution A away from fire sources.

7.2) Storage:

Store according to product instruction for use and labels (generally at 2-8 ℃).

This kit is for *in vitro* diagnostic use, professional use only. Read and follow all warnings and precautions in product instruction for use and labels.

8) Exposure control/Personal protection:

8.1) Control parameters

No special measures required.

8.2) Exposure controls

Respiratory protection: Ensure adequate ventilation.

Hand protection: Protective gloves.

Eye protection: Safety goggles or face shield.

Body protection: Lab coat.

9) Physical and chemical Properties:

Appearance	Aqueous liquids, exception are the solid microwell plate.		
Color	Nearly colorless, exceptions are **HBsAg • Peroxidase Solution** , which is yellow. And **Zero Control** is light yellow.		
Odor	Nearly odorless		
pH	Most of the liquid components are between pH 6~8, exceptions are the following acidic solutions: **TMB Substrate Solution A** at pH~3, **TMB Substrate Solution B** at pH~5, and **1 N Sulfuric Acid** at pH<2.		
Melting point	Not established	**Boiling point**	Not established
Flash point	Not established		
Evaporation rate	Not established		
Fire hazard	Keep **TMB Substrate Solution A** away from fire sources		
Vapor pressure	Not established	**Vapor density**	Not established
Density	Not established		
Solubility	The liquid components are soluble in water.		
Patition coefficient	Not established		
Auto igniting	Not established		
Decomposition temperature		Not established	
Viscosity	Not established		
Danger of explosion	Not established		

10) Stability and Reactivity:

10.1) Chemical stability / reactivity

No data available

10.2) Conditions to avoid:

None known when used as intended.

10.3) Materials to avoid:

None known when used as intended.

And don't let the acidic solutions to contact with strong bases, oxidizing agents and metals.

10.4) Dangerous decomposition products:

#	Components	Specific Hazards
1	HBsAg Plate	CO.
2	HBsAg・Peroxidase Solution	CO, NO_x, SO_x, Hg.
3	Zero Control	CO, NO_x, SO_x, N_2.
4-9	Standards	CO, NO_x, SO_x, N_2.
10	TMB Substrate Solution A	CO, NO_x, SO_x.
11	TMB Substrate Solution B	CO.
12	Conc. Washing Solution D (20X)	CO
13	1 N Sulfuric Acid	SO_x.

11) Toxicological Information:

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is

11.1) Acute Toxicity:	
Toxicity:	Acute toxicity will not occur if used and stored according to the product instruction for use.
Irritation:	May cause irritation to skin, mucous membranes and eyes.
Corrosivity:	Component **1 N Sulfuric Acid** may causes skin, eye damage and chemical burns to the respiratory tract.
STOT-Single Exposure:	No data available, **TMB substrate A** may affects visual and central nervous system.
STOT-Repeated Exposure:	No data available, **TMB substrate A** may affects visual and central nervous system.
Aspiration Hazard:	No data available
11.2) Chronic Toxicity or Long Term Toxicity:	

Sensitization:	May cause sensitization to mucous membranes and eyes.
Carcinogenicity/Mutagenicity:	Component **1 N Sulfuric Acid,** (Sulfuric acid, CAS# 7664-93-9: IARC Group 1, is carcinogenic to humans, which is diluted to 4.94% in **1 N Sulfuric Acid**)
Reproductive hazard:	No data available.
11.3) Biohazard Potential:	
Human/ animal sourced mixture in #1~10 components, handle as potentially infectious. Patient blood samples analyzed with the kit represent an unknown, heightened biohazard, too.	

12) Ecological Information

Components of this kit were not tested; the following data is according to the ingredients vendor safety data sheets.

12.1) Toxicity	
Methanol	No data available
Sulfuric acid	No information available
12.2) Persistence and degradability	
Methanol	92 % (by BOD), 99 % (by TOC), 100 % (by GC) *The substance was determined as "Ready biodegradability" under the Chemical Substances Control Law.
Sulfuric acid	No information available
12.3) Bioaccumulative potential	
Methanol	BCF: 0.2
Sulfuric acid	No information available
12.4) Mobility in soil	
Methanol	Mobility in soil Log Pow: -0.82/-0.66 Soil adsorption (Koc): No data available Henry's Law constant(PaM^3/mol): 0.4
Sulfuric acid	No information available
12.5) Results of PBT and vPvB assessment	
Methanol	N/A
Sulfuric acid	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.
12.6) Other adverse effects	
Methanol	No data available
Sulfuric acid	Biological effects: Forms corrosive mixtures with water even if diluted. Harmful effect due to pH shift. Endangers

	drinking-water supplies if allowed to enter soil or water. Further information on ecology. Discharge into the environment must be avoided.

13) Disposal Considerations:

Prior to disposing patient specimens and kit components as general waste; it should be treated in accordance with the local practice of potential bio-hazardous waste or treated as follows: Both liquid and solid waste should be autoclaved at +121 ℃ for at least 30 minutes. Solid waste can also be incinerated. Non-acidic liquid waste can be treated with sodium hypochlorite diluted to a final concentration of 1 %. Acidic liquid wastes must be neutralized before treatment with sodium hypochlorite as mentioned above and should stand for 30 minutes to obtain effective disinfection.

14) Transport information

14.1) Land Transport ADR/RID:

1N Sulfuric Acid: ADR/RID Class: 8 Corrosive Substances
UN Number: UN2796
Packaging Group: II
Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.
Other components: ADR/RID Class: None

14.2) Maritime Transport IMDG:

1N Sulfuric Acid: IMDG Class: 8
UN Numbe: UN2796
Packaging Group: II
Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.
Other components: IMDG Class: None

14.3) Air Transport ICAO-Ti and IATA_DGR:

1N Sulfuric Acid: ICAO/IATA Class: 8
UN Number: UN2796
Packaging Group: II
Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.
Other components: ICAO/IATA Class: None

15) Regulations:

15.1) Product Related Hazard Information:

Observe the general safety regulations when handling the kit, its components and specimens.

15.2) Labeling and classification according to GLOBALLY HARMONISED SYSTEM (GHS), REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (CLP)

15.3) Information about limitation of use:

The kit and its components are for in vitro diagnosis use and for professional use only.

16) Other Information:

This SDS is based on our present knowledge. However, it is intended only as a guide to the appropriate precautionary handling of the kit and its components for professional use. Individuals receiving this SDS must exercise their independent judgment in determining its appropriateness for a particular purpose.