1) Product and company identification:

Product: In Vitro Reagents Product Code: 4SBE3

Company: GENERAL BIOLOGICALS CORP.

Address of the company: #6, INNOVATION FIRST ROAD, SCIENCE PARK, HSIN CHU, TAIWAN, R.O.C.

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

Fax number of the company: 886-3-5779227 E mail of the company: SALE.GROUP@gbc.com.tw

2) Composition/information on ingredients:

2.1) Chemical Characterization: preparation

2.2) Description: Kit of components listed below with non-hazardous additions.

No.	Components	Physical appearance	96-tests
1	HBsAg Plate	Solidin aluminum foil	1 plate
2	HBsAg HRPO Solution	Liquid in plastic bottle	1 bottle, 7 ml/btl
3	HB Negative Control	Liquid in plastic bottle	1 bottle, 1.6 ml/btl
4	Anti-HBs Positive Control	Liquid in plastic bottle	1 bottle, 1.1 ml/btl
5	Washing Solution D (20X)	Liquid in plastic bottle	1 bottle, 52 ml/btl
6	TMB substrate Solution A	Liquid in plastic bottle	1 bottle, 10 ml/btl
7	TMB Substrate Solution B	Liquid in plastic bottle	1 bottle, 10 ml/btl
8	2N Sulfuric Acid	Liquid in plastic bottle	1 bottle, 12 ml/btl

2.3) Dangerous Components:

Component	CAS No.	Ingredient	Content	S phrases	R phrases
(2)	Not found	Human/Animal Sourced Preparation	40%	Not found	Not found
	77-86-1	Tris	<2 %	26-36	36/37/38
	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	54-64-8	Thimerosal	<0.1 %	13-28-36-45	26/27/28-33
	Not found	Horse-radish peroxidase	Trace	Not found	Not found
(3)	Not found	Human/Animal Sourced Preparation	100%	Not found	Not found
	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	54-64-8	Thimerosal	<0.1 %	13-28-36-45	26/27/28-33
(4)	Not found	Human/Animal Sourced Preparation	100%	Not found	Not found
	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
	54-64-8	Thimerosal	<0.1 %	13-28-36-45	26/27/28-33

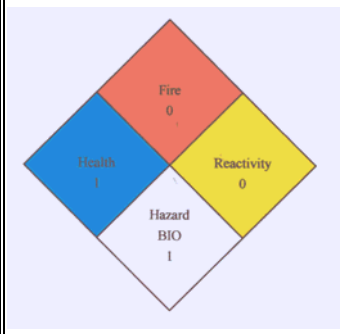
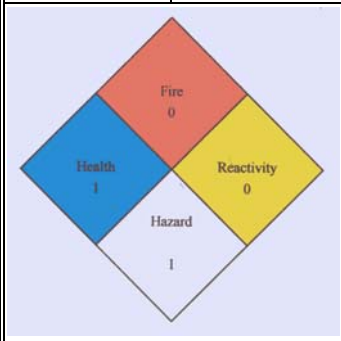
	Component	CAS No.	Ingredient	Content	S phrases	R phrases
	(5)	54827-17-7	3,3'5,5'-Tetramethylbenzidine	<0.04 %	26-22-36	20/21/22-36/37/38-40
		67-68-5	Dimethyl sulfoxide	<5 v/v%	26-36-23	36/37/38
		67-56-1	Methanol	5 v/v %	7-16-24-45	11-23/25
		56-81-5	Glycerol	<15 v/v %	26-36	36/38
	(6)	1405-41-0	Gentamycin Sulfate	<0.01 %	45-36/37/39-22	61-36/38-42/43
		7722-84-1	Hydrogen peroxide	< 0.1%	17-45-26-36/37/39	8-34
	(8)	7664-93-9	Sulfuric Acid	<6 v/v %	26-30-45	35

2.4) Additional Information:

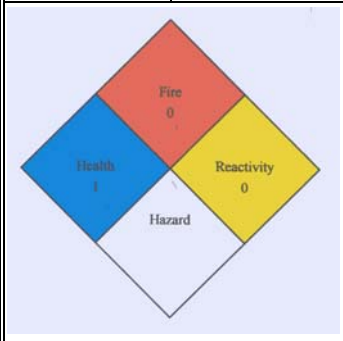
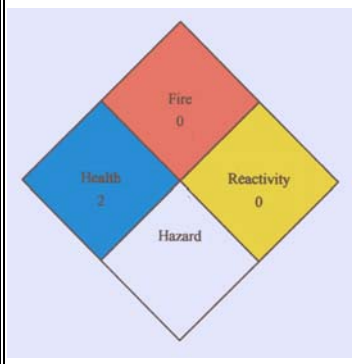
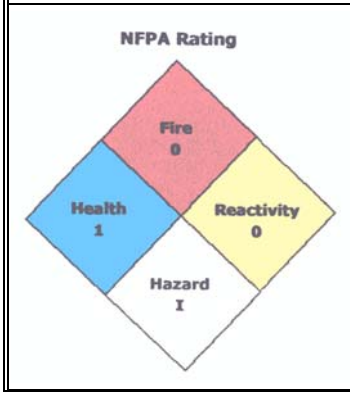
The components 1. to 4 contain materials of human or animal origin which has been inactivated at 56℃ for 1 hour. Since no test method offers complete assurance that infectious agents are absent, these components should be handled as potential infectious.

3) Hazards Identification:

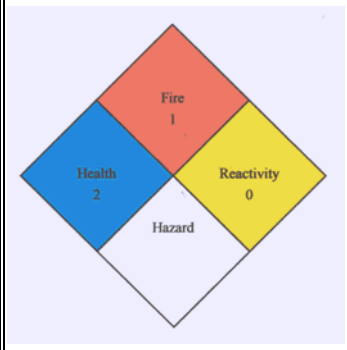
3.1) Hazard description:

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Human/ Animal Sourced Preparation Potential Biohazard		1. Inhalation 2. Skin contact 3. Eye contact 4. Ingestion	Potential biohazard	Potential biohazard, should be autoclaved before disposal.	No
					
Tris Buffer	Irritation 	1. Skin contact 2. Eye contact 3. Ingestion	1. May cause irritation to skin. Symptoms include redness, itching, and pain. 2. May cause irritation, redness, and pain. 3. May be harmful, cause irritation and reddening to the mucous membranes. Symptoms may include nausea, vomiting and diarrhea. Estimated lethal dose: 50 gm.	No (concentration <2 %)	No (Aqueous solution)
					

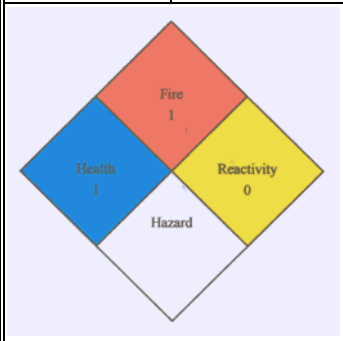
To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Gentamycin Sulfate in Solution Irritation 		1. Skin contact 2. Eye contact 3. Ingestion	1. May cause skin irritation: redness or itching. May cause systemic poisoning. 2. May cause eye irritation/sensitization. May cause systemic poisoning. 3. May be harmful, cause irritation to the mucous membranes. May cause systemic poisoning.	No (concentration <0.01 %)	No (Aqueous solution)
Thimerosal in Solution Harmful 		1. Skin contact 2. Eye contact 3. Ingestion	1. May be harmful through skin contact. 2. May be harmful through eyes contact. 3. Harmful by ingestion, ORL Rat LD_{50}: 75mg/kg^{-1}.	Contains mercury ($C_9H_9HgNaO_2S$ concentration <0.1 %)	No (Aqueous solution)
Horse-radish peroxidase Solution Irritation 		1. Skin contact 2. Eye contact 3. Ingestion 	a. There is at present no information or indication of hazardous property. b. May cause irritation. c. May cause allergic reaction to a small percentage of the population who exhibit an allergic reaction to enzymes.	No (concentration is very low)	No (Aqueous solution)

To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
3,3'5,5'-Tetramethyl-Benzidine Solution	Harmful or irritation 	Skin contact Eye contact Ingestion	Harmful, irritation, should be handled as a potential carcinogen.	No (concentration <0.1 %)	No (Aqueous solution containing dimethyl sulfoxide and methyl alcohol)
					
Dimethyl Sulfoxide in Aqueous Solution Irritation		1. Inhalation 2. Skin contact 3. Eye contact 4. Ingestion	1. Irritation, nausea, vomiting, headache, dizziness. 2. Irritation, allergic reactions, blisters, rash, itching, nausea, vomiting, diarrhea, chest pain, headache, drowsiness, blood disorders. 3. Irritation, blurred vision 4. Nausea, vomiting, diarrhea, stomach pain, drowsiness.	No (concentration <5 v/v%)	No (Aqueous solution)
					

To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Methanol Aqueous Solution Irritation Toxic 		1. Inhalation 2. Skin contact 3. Eye contact 4. Ingestion	1. Cause irritation to respiratory tract. Affects central nervous system, especially optic nerve. Cause dizziness, nauseam muscle weakness, narcosis, respiratory failure. 2. Cause irritation to skin. 3. Cause irritation to eyes. 4. Harmful if digested. Affects central nervous system, especially optic nerve. Cause dizziness, nauseam muscle weakness, narcosis, respiratory failure. Can produce blindness (100 ml can be tatal).	No (Concentration <45 v/v %)	No (Aqueous solution)
Hydrogen peroxide Aqueous Solution (< 0.1%) 	Very Mild Oxidizing 	Skin contact Eye contact Ingestion	No	No (concentration < 0.1%)	No (Aqueous solution)

To be continued

Ingredient	Classification & Symbol	Routes of Entry	Health Hazards	Environmental Hazards	Fire/explosive Hazards
Dilute Sulfuric Acid Aqueous Solution (<6 v/v %) Corrosive		1. Inhalation	1. May cause severe irritation of the respiratory tract with sore throat, coughing, shortness of breath and delayed lung edema. May Causes chemical burns to the respiratory tract. Inhalation may be fatal as a result of spasm, inflammation, edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema. Aspiration may lead to pulmonary edema. May cause systemic effects.	No (concentration <6 v/v %)	No (Aqueous solution)
		2. Skin contact	2. Causes skin burns. Continued contact can cause tissue necrosis. May cause skin rash, and cold and clammy skin with cyanosis or pale color.		
		3. Eye contact	3. Causes eye burns. May cause chemical conjunctivitis and corneal damage.		
		4. Ingestion	4. May cause severe and permanent damage to the digestive tract. Causes gastrointestinal tract burns. May cause systemic toxicity with acidosis. May cause perforation of the digestive tract.		
		5. Cancer hazard. Mutation.			

3.2) Classification System:

The classification is according to GLOBALLY HARMONISED SYSTEM FOR THE CLASSIFICATION AND LABELLING OF CHEMICALS (May 2001) and NFPA hazard labels.

4) First-aid Measures:

General Information	No special measures required.
Inhalation	Supply fresh air. Seek medical advice in case of complaints.
Ingestion	Rinse mouth thoroughly with water. Seek medical advice in case of complaints.
Contact with eyes	Wash with copious amounts of water. Seek medical advice in case of complaints.
Contact with skin	Wash thoroughly with water. Seek medical advice in case of complaints.
Protection of First-aiders	Wearing of protective gloves and avoiding the generation of aerosols.

5) Fire Fighting Measures:

Suitable extinguishing agents: CO_2, powder or water spray.
Fight larger fires with water spray or alcohol resistant foam.

Special Protective Equipment: No special measures required.

Specific Hazards:

Components	Specific Hazards
1. Plate	CO.
2. HRPO Conjugate Solution	CO, NO_x, SO_x, Hg.
3. Negative Control	CO, NO_x, SO_2, Hg.
4. Positive Control	CO, NO_x, SO_x, Hg.
5. Washing Solution D (20X)	CO.
6. TMB substrate Solution A	CO, NO_x, SO_x.
7. TMB Substrate Solution B	CO.
8. 2N Sulfuric Acid	SO_x.

6) Accidental Release Measures:

Personal Precautions: Wear protective gloves and avoid the generation of aerosols.
Keep unprotected persons away.
Ensure adequate ventilation.

Environmental Precautions: Treated (inactivated) as biological hazardous contamination.

Methods for Cleaning Up:

Components	Methods for Cleaning Up
2. HRPO Conjugate Solution	Inactivated with Sodium Hypochlorite Solution prior to clean with plenty of water.
3. Negative Control	
4. Positive Control	
5. Washing Solution D (20X)	Clean with plenty of water.
6. TMB substrate Solution A	
7. TMB Substrate Solution B	
8. 2N Sulfuric Acid	

7) Handling and Storage:

7.1) Handling:

Technical Measures: No special measures required.

Precautions: Handled as biohazards.
Wear protective gloves and avoid the generation of aerosols.
Keep TMB Solution A away from fire sources.

Specific Safe Handling Advice: No special measures required.

7.2) Storage:

Technical Measures: No special measures required.

Storage conditions: Store in 2 ～ 8℃.

Incompatible products: No special measures required.

Packaging Materials: No special measures required.

8) Exposure Control/Personal Protection:

8.1) Engineering Measures:

Additional Information about design of technical facilities: No, see item 7).

8.2) Specific Control Parameters:

Ingredients with limit values that require monitoring at the workplace: No.

Additional Information: No special measures required.

8.3) Personal Protective equipment:

Respiratory Protection: No special measures required.

Hand Protection: Wear protective gloves.

Eye Protection: No special measures required.

Skin and Body Protection: Wear protective gown.

8.4) Hygiene Measures: Handled as biohazards.

9) Physical and chemical Properties::

9.1) Physical Properties:

Component	Form	Color	Odor	m.p.	b.p.	Flash Point	Self-ignition
1. plate	solid	colorless	odorless	N/A	N/A	N/A	N/A
2. HRPO Conjugate Solution	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
3. Negative Control	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
4. Positive Control	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
5. Washing Solution D (20X)	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
6. TMB substrate Solution A	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
7. TMB Substrate Solution B	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined
8. 2N Sulfuric Acid	Liquid	Nearly colorless	Nearly odorless	Not determined	Not determined	Not determined	Not determined

9.2) Chemical Properties:

Component	Danger of explosion	Density	Solubility in water	Organic Solvents Content	Water content
1. plate	No	N/A	N/A	0	0
2. HRPO Conjugate Solution	No	Not determined	Miscible	0	Aqueous Solution
3. Negative Control	No	Not determined	Miscible	0	Aqueous Solution
4. Positive Control	No	Not determined	Miscible	0	Aqueous Solution
5. Washing Solution D (20X)	No	Not determined	Miscible	0	Aqueous Solution
6. TMB substrate Solution A	No	Not determined	Miscible	＜50%	Aqueous Solution
7. TMB Substrate Solution B	No	Not determined	Miscible	0	Aqueous Solution
8. 2N Sulfuric Acid	No	Not determined	Miscible	0	Aqueous Solution

10) Stability and Reactivity:

10.1) Thermal decomposition/Conditions to be avoid:

Decomposition will not occur if used and stored according to the package insert.

10.2) Materials to be avoided:

Please use the kit in accordance with the package insert.

10.3) Dangerous Reactions:

No dangerous reactions known.

10.4) Dangerous decomposition products:

Components	Dangerous decomposition products
1. Plate	CO.
2. HRPO Conjugate Solution	CO, NO_x, SO_x, Hg.
3. Negative Control	CO, NO_x, SO_2, Hg.
4. Positive Control	CO, NO_x, SO_x, Hg.
5. Washing Solution D (20X)	CO.
6. TMB substrate Solution A	CO, NO_x, SO_x.
7. TMB Substrate Solution B	CO.
8. 2N Sulfuric Acid	SO_x.

11) Toxicological Information: :

11.1) Acute Toxicity:

Acute toxicity will not occur if used and stored according to the package insert.

11.2) Local Effects:

Components	Local Effects
1. Plate	No.
2. HRPO Conjugate Solution	May cause irritation to skin, mucous membranes and eyes.
3. Negative Control	May cause irritation to skin, mucous membranes and eyes.
4. Positive Control	May cause irritation to skin, mucous membranes and eyes.
5. Washing Solution D (20X)	No.
6. TMB substrate Solution A	May cause irritation to skin, mucous membranes and eyes.
7. TMB Substrate Solution B	May cause irritation to skin, mucous membranes and eyes.
8. 2N Sulfuric Acid	May cause irritation to skin, mucous membranes, eyes and respiratory tract. May cause chemical burns to the respiratory tract.

11.3) Sensitization:

Components	sensitization
1. Plate	No.
2. HRPO Conjugate Solution	May cause sensitization to mucous membranes and eyes.
3. Negative Control	May cause irritation to skin, mucous membranes and eyes.
4. Positive Control	May cause irritation to skin, mucous membranes and eyes.
5. Washing Solution D (20X)	No.
6. TMB substrate Solution A	May cause irritation to mucous membranes and eyes.
7. TMB Substrate Solution B	No.
8. 2N Sulfuric Acid	No.

To be continued

11.4) Chronic Toxicity or Long Term Toxicity:

Components	Chronic Toxicity or Long Term Toxicity
1. Plate	No.
2. HRPO Conjugate Solution	May cause systemic poison.
3. Negative Control	May cause systemic poison.
4. Positive Control	May cause systemic poison.
5. Washing Solution D (20X)	No.
6. TMB substrate Solution A	May affects central nervous system.
7. TMB Substrate Solution B	No.
8. 2N Sulfuric Acid	May cause systemic toxicity with acidosis.

11.5) Carcinogenicity/Mutagenicity:

Components	Carcinogenicity/Mutagenicity
1. Plate	Not a carcinogen/mutagen.
2. HRPO Conjugate Solution	Not a carcinogen/mutagen.
3. Negative Control	Not a carcinogen/mutagen.
4. Positive Control	Not a carcinogen/mutagen.
5. Washing Solution D (20X)	Not a carcinogen/mutagen.
6. TMB substrate Solution A	May be a carcinogen/mutagen.
7. TMB Substrate Solution B	Not a carcinogen/mutagen.
8. 2N Sulfuric Acid	IARC Category 1

11.6) Additional Toxicological Information:

Not found.

12) Ecological Information (Possible environmental Effects behavior and fate):

2N Sulfuric Acid: Water hazard class 2: hazardous for water.

Other liquid components: Water hazard class 1: slightly hazardous for water.

Do not allow undiluted liquid components or large quantities of the liquid components to reach ground water, water course or sewage system.

13) Disposal Considerations:

Components	Recommended Disposal Methods for components/contaminated components/used components.
1. Plate	Treated as potential infectious materials before disposal.
2. HRPO Conjugate Solution	Treated as potential infectious materials before disposal.
3. Negative Control	Treated as potential infectious materials before disposal.
4. Positive Control	Treated as potential infectious materials before disposal.
5. Washing Solution D (20X)	Diluted with large quantities of water.
6. TMB substrate Solution A	No special measures required.
7. TMB Substrate Solution B	No special measures required.
8. 2N Sulfuric Acid	Neutralized with base and/or diluted with large quantities of water.
Specimens	Treated as potential infectious materials before disposal.

14) Transport Information

14.1) Land Transport ADR/RID:

2N 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:

2N Sulfuric Acid: IMDG Class: 8
UN Number: 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:

2N 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 according to EU guidelines/NFPA chemical Hazard Labels:

The kit including its components will be classified and marked in accordance with EU Directives/NFPA Chemical Hazard Labels.

15.3) Information about limitation of use:

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

15.4) Code letter, risk phrases, safety phrases and hazard designation of the kit and its components:

Please see 2.3) and 3.1) of this MSDS.

16) Other Information:

This MSDS 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 MSDS must exercise their independent judgment in determining its appropriateness for a particular purpose.