



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 1 of 10

Effective date: Jan 2008

Revision C

1-Product and Company Identification

PRODUCT NAME: Ribosomal IgG,A,M Test Kit
SUPPLIER:
Name: Trinity Biotech USA
Address: 2823 Girts Rd.
Jamestown, NY 14701
USA
Phone number: (716) 483-3851
Fax number: (716) 488-1990
Emergency phone number: Contact national poisons unit.
Ireland 01- 837 9964
Belgium (+31) 30 2748888
France (+331).40.37.04.04
USA 1800-603 8076

2-Composition / information on components

PREPARATION

Chemical nature: (composition with the main components and dangerous components)

Components contributing to the hazard:

TMB substrate/chromogen Product Code # 525700

Chemical	Concentration	Units	CAS	EC Hazard symbol	R&S phrases
Dimethyl Sulfoxide	≤ 1.0 %	ml/ml	67-68-5	Not applicable	R 36/37/38 S 26,36,23
Hydrogen Peroxide	≤ 0.03 %	ml/ml	7722-84-1	Not applicable	R 36/38 S 36

Stop Solution Product Code # 915401

Chemical	Concentration	Units	CAS	EC Hazard symbol	R&S phrases
Sulfuric Acid	5%	ml/ml	7664-93-9	Xi Irritant	R 36/38 S (1/2), 26,36,23

Wash Buffer Product Code # 827402

Chemical	Concentration	Units	CAS	EC Hazard symbol	R&S phrases
Hydrochloric Acid	0.24 %	ml/ml	7647-01-0	Not applicable	R 34/37 S (1/2), 26, 45
Trizma Base	0.03 %	g/ml	77-86-1	Not applicable	R 36/37/38 S 26,36
Tween 80	4.3 %	g/ml	9005-65-6	Category 3 Harmful	R 40 S 36

This preparation also contains Blue food dye and Proclin as preservative.



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 2 of 10

Effective date: Jan 2008

Revision C

Components presenting a hazard a danger: (dangerous products with concentrations under the hazard threshold)

High Positive Control Product Code # 3877-1

Chemical	Concentration and Units
Sodium Azide	< 0.1 % g/ml

This preparation also contains Penicillin/Streptomycin and Ribosomal positive human serum.

Low Positive Control Product Code # 3877-4

Chemical	Concentration and Units
Sodium Azide	< 0.1 % g/ml

This preparation also contains Penicillin/Streptomycin and Ribosomal positive human serum.

Calibrator Product Code # 3877-2

Chemical	Concentration and Units
Sodium Azide	< 0.1 % g/ml

This preparation also contains Penicillin/Streptomycin and Ribosomal positive human serum.

Negative Control Product Code # 3877-3

Chemical	Concentration and Units
Sodium Azide	< 0.1 % g/ml

This preparation also contains Penicillin/Streptomycin and Ribosomal negative human serum.

Conjugate


This preparation contains Antihuman IgG,A,M conjugated to horse radish peroxidase, a conjugate stabilizer, and Proclin, Gentamycin sulfate and Bromonitrodioxane as preservatives.

Serum Diluent Product Code # 616434

Chemical	Concentration and Units
Sodium Phosphate, Monobasic	0.02 % g/ml
Sodium Phosphate, Dibasic	0.02 % g/ml
Tween 20	0.05 % g/ml

This preparation also contains BSA, Casein Hydrolysate, Enzymatic, Yellow food dye and Proclin as preservative.

Intended use: *In vitro* diagnostic for professional use.

 <p>TRINITY BIOTECH USA</p>	<p style="text-align: right;">MSDS</p> <p>NAME OF PRODUCT: Ribosomal TEST KIT Product Code: 2338770</p> <p>MSDS Number: 8770-MS</p> <p>Page 3 of 10</p>
<p>MATERIAL SAFETY DATA SHEET</p>	<p>Effective date: Jan 2008 Revision C</p>

3-Hazard Identification

MOST IMPORTANT HAZARDS:

The human serum components used in the preparation of the Controls and Calibrator in this kit have been tested by an FDA approved method for the presence of antibodies to human immunodeficiency virus 1 & 2 (HIV 1&2), hepatitis C (HCV) as well as hepatitis B surface antigen and found negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus, or other infectious agents are absent, specimens and human-based reagents should be handled as if capable of transmitting infectious agents.

LABEL PRECAUTIONARY STATEMENTS

Stop Solution Product Code # 915401

Xi Irritant

FOR **SULFURIC ACID** IN STOP SOLUTION PREPARATION: **DANGER!** CORROSIVE LIQUID AND MIST CAUSE SEVERE BURN TO ALL BODY TISSUE. MAY BE FATAL IF SWALLOWED OR CONTACTED WITH SKIN. HARMFUL IF INHALED. AFFECTS TEETH. CANCER HAZARD. STRONG INORGANIC ACID MISTS CONTAINING SULPHURIC ACID CAN CAUSE CANCER. RISK OF CANCER DEPENDS ON DURATION AND LEVEL OF EXPOSURE. WEAR SUITABLE CLOTHING. IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE).

Wash Buffer Product Code # 827402

Harmful

FOR **TWEEN 80** IN WASH BUFFER PREPARATION: HARMFUL. POSSIBLE RISK OF IRREVERSIBLE EFFECTS. WEAR SUITABLE PROTECTIVE CLOTHING. AVOID INHALATION, AVOID CONTACT WITH EYES, SKIN, AND CLOTHING. AVOID PROLONGED OR REPEATED EXPOSURE. IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS. CALL A PHYSICIAN. IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. IN CASE OF CONTACT, IMMEDIATELY WASH SKIN WITH SOAP AND COPIOUS AMOUNTS OF WATER. IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.

Adverse human health effects:

The following general hazard warnings apply to all the kit components

Potential Routes of Exposure:

Target organs: Skin Contact, eye contact, accidental ingestion, inhalation



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 4 of 10

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision C

Eye:

Excessive contact may cause eye irritation, redness, pain, burns
Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulphuric acid. Symptoms may include blurred vision, redness, pain, and burns to eye tissue.

Skin:

Direct or repeated contact may cause skin irritation. May be absorbed through the skin causing systemic effects (see effects for inhalation and ingestion). Dermatitis
Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulfuric acid. Symptoms may include redness, pain, and burns to the skin. Circulatory collapse with clammy skin, weak and rapid pulse, shallow respirations, and scanty urine may follow ingestion or skin contact.

Inhalation:

Do not breathe vapor.
Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulfuric acid. Symptoms may include irritation of the nose and throat, labored breathing, as well as lung edema, damage to the mucous membranes and upper respiratory tract.

Accidental ingestion:

General –Abdominal pain. Shortness of breath. Unconsciousness. Vomiting. Sweating. Drowsiness.
Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulphuric acid. Symptoms may include severe burns of the mouth, throat, and stomach. Circulatory collapse with clammy skin, weak and rapid pulse, shallow respirations, and scanty urine may follow ingestion or skin contact. Circulatory shock is often the immediate cause of death. May cause sore throat, vomiting, diarrhea.

Chronic Toxicity

Prolonged or repeated contact may cause allergic dermatitis (redness, irritation, rash), may cause sensitization.
Sulfuric Acid: Long term exposure to mist or vapors may cause damage to teeth. Chronic exposure to mists containing sulphuric acid is a cancer hazard.

Reproductive and Developmental Toxicity:


None identified.

Carcinogenicity:

None identified for DMSO. Carcinogenicity applies to "strong inorganic acid mists containing sulfuric acid" but not to sulfuric acid or sulfuric acid solutions. Tween 80 is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP OR EPA Classification

Medical Conditions Aggravated by Exposure:

DMSO: Eye Disorders, Skin disorders, Liver or Kidney disorders. Topical application enhances dermal absorption of many other chemicals, including drugs/allergens of moderate molecular weight.
Sulfuric Acid: Pre-existing skin disorders, eye problems, respiratory function may be more Susceptible to the effects of the substance.

 <p>TRINITY BIOTECH USA</p>	<p style="text-align: right;">MSDS</p> <p>NAME OF PRODUCT: Ribosomal TEST KIT Product Code: 2338770</p> <p>MSDS Number: 8770-MS</p> <p>Page 5 of 10</p>
<p>MATERIAL SAFETY DATA SHEET</p>	<p>Effective date: Jan 2008 Revision C</p>

Environmental effects:

See section 12 – Ecological Information

EC classification of the preparation:

TMB Substrate solution containing DMSO and Sulfuric acid are classified as irritants. As only a minimal amount of the preparation is provided with the TMB substrate and Stop Solution, container and packaging are not marked with the irritant symbol. Wash Buffer containing Tween 80 is classified as harmful. Warnings are provided in the package insert with regards to the use of this product and it is recommended that protective clothing be worn.

4-First-aid measures

The following general first aid measures apply to all components of the kit.

Inhalation:

Immediately move to fresh air and notify medical personnel. If not breathing give artificial respiration. If breathing difficult, give oxygen.

Skin contact:

Immediately wash thoroughly with soap and water for 15 minutes and notify medical personnel. Remove and wash contaminated clothing and shoes.

Eye contact:

Immediately flush eyes thoroughly with water for at least 15 minutes and notify medical personnel.

Ingestion:

If swallowed, wash out mouth with water and notify medical personnel. Remove and wash contaminated clothing and shoes.

5-Fire-fighting measures

The following general measures apply to all components of the kit.

Extinguishing media:

Use dry chemical foam or carbon dioxide. Water may not be effective.

Specific hazards:

For DMSO vapors may flow along surfaces to distant ignition sources and flash back. Closed containers exposed to heat may explode.

For sulphuric acid contact with most metals causes formation of flammable and explosive hydrogen gas.

Specific methods of fire-fighting:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face-piece operated in the pressure demand or other positive pressure mode. Structural fire-fighter's protective clothing is ineffective for fires involving sulphuric acid. Stay away from sealed containers.



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 6 of 10

Effective date: Jan 2008

Revision C

6-Accidental release measures

Personal precautions:

Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Methods of cleaning up:

Contain liquid when possible. Use non sparking tools and equipment. Absorb with an inert material (e.g., vermiculite, dry sand, earth), and place in a chemical waste container. Do not use combustible materials, such as saw dust. Ventilate area and wash spill site after material pickup is complete.

Environmental precautions:

Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulation. Do not flush to sewers, storm drains, surface waters, and soil.

7-Handling and storage

Avoid contact with skin, eyes or clothing. Use adequate ventilation or minimize exposures to mists or aerosols. Wash thoroughly after handling. DO NOT permit contact with acids and other incompatible substances. Store at 2-8°C

8-Exposure control / Personal protection

Occupational Exposure Limits:

There are no established exposure limits for this product. However, the following exposure limits exist for the following hazardous ingredients:

Ingredients:	OSHA PEL	ACGIH TLV	Other
DMSO:	Not established	Not established	
Sulfuric Acid:	1 mg/m ³	1 mg/m ³	3 mg/m ³ (STEL)
Tween 80	Not established	Not established	

Personal Protective Equipment:

Eye and Face Protection:

Wear safety glasses with side shield, or full face shield if eye contact is likely. The choice of protection should be based on the job activity and potential for exposure to eyes and face.

Respiratory protection:

When handling bulk quantities or for long durations where aerosolization of material is likely, wear a NIOSH – approved air purifying respirator.

Skin and body protection:

Wear gloves, lab coat, or other protective over-garment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 7 of 10

Effective date: Jan 2008

Revision C

Hygiene measures:

Wash hands immediately after handling materials (especially before eating, drinking or smoking). Decontaminate or discard protective equipment after each use.

Remove personal protective equipment when leaving work area.

9-Physical and chemical properties

Not Applicable

10-Stability and reactivity

The kit should only be used as instructed in the package insert.
See pack insert for further information of kit stability.

11-Toxicological information

Toxicological information is supplied for DMSO, Sulfuric Acid, and Tween 80 only. Other components of the preparation are not supplied at levels or quantities currently thought to have toxicological effects.

Dimethyl sulphoxide (DMSO) is present at $\leq 1\%$ in the TMB Substrate/Chromogen. Rtecs # pv6210000

Sulfuric Acid is present at 5 % in the Stop Solution.

Tween 80 is present in 4.8% in Wash Buffer

Inhalation:

DMSO: No data

Sulfuric Acid: LD₅₀ = 510 mg/m³/2H (rat)

Tween 80:

Skin (Irritancy and Acute Toxicity):

DMSO: caused mild irritation to rabbit skin at 10 and 500 mg/24 hours.

Skn LD₅₀ = 40 g/kg (rat). Skn LD₅₀ = 50 g/kg (mouse). Ipr LD₅₀ = 8200 mg/kg (rat). Scu LD₅₀ = 12 gm/kg (rat). Scu LD₅₀ = 14 gm/kg (mouse). Ipr LD₅₀ = 2500 mg/kg (mouse)

Sulfuric Acid: No info.

Tween 80: Ipr LD₅₀ = 6804 mg/kg (rat). Ipr LD₅₀ = 7600 mg/kg (mouse)

Eye (Irritancy and Acute Toxicity):

DMSO: caused mild irritation to rabbit eye at 100 and 500 mg for 24 hours.

Sulfuric Acid: Standard Draize, eye, rabbit, 250 µg (severe)

Tween 80: caused mild irritation to rabbit eye at 150 mg.

Ingestion:

DMSO: LD₅₀ = 14500 mg/kg (rat). LD₅₀ = 7920 mg/kg (mouse). LD₅₀ = >10gm/kg (dog).

LD₅₀ = 12 gm/kg (chicken). LD₅₀ = 21400 mg/kg (mam).

Sulfuric Acid: LD₅₀ = 2140 mg/kg (rat)

Tween 80: LD₅₀ = 34500 ul/kg (rat). LD₅₀ = 25 gm/kg (mouse). LD₅₀ = 25 gm/kg (mam).



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 8 of 10

Effective date: Jan 2008

Revision C

Sensitisation:

DMSO: No data
Sulfuric Acid: No data
Tween 80: No data

Chronic toxicity or long term toxicity:

DMSO: target organs: eyes, skin to the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Sulfuric Acid: Long term exposure to mist or vapors may cause damage to teeth. Chronic exposure to mists containing sulphuric acid is a cancer hazard.
Tween 80: Target organ data: Behavioral (altered sleep time), cardiac (other changes) This product is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP or EPA classification. the chemical, physical, and toxicological properties have not been thoroughly investigated.

Specific effects:

Carcinogenicity

DMSO: None identified
Sulfuric Acid: None identified
Tween 80: This product is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP or EPA classification.

Mutagenicity

DMSO: None identified
Sulfuric Acid: None identified
Tween 80: None identified

Reproduction toxicity

DMSO: None identified
Sulfuric Acid: None identified
Tween 80: None identified

12-Ecological information

DMSO: Does not biodegrade in soil, may leach into groundwater, may evaporate some. May evaporate in water. Not expected to significantly bioaccumulate. In air may be moderately degrade reaction with photochemically produced hydroxyl radicals. Environmental toxicity not known.
Sulfuric Acid: May leach into ground water. In air removed to moderate extent by wet deposition. Removed to moderate extent by dry deposition. Environmental toxicity- LD₅₀ Flounder 100 to 330 ng/l/48 hr aerated water/ Conditions of bioassay not specified. LD₅₀ Shrimp 80-90 mg/l/48 hr aerated water / Conditions of bioassay not specified. LD₅₀ prawn 42.5 ppm/48 hr salt water / conditions of bioassay not specified. May be toxic to aquatic life.
Tween 80: Data Not Yet Available

13-Disposal considerations

Dispose of materials in this kit according to Federal, State and Local Requirements.



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 9 of 10

Effective date: Jan 2008

Revision C

14-Transport information

Land transport ARD / RID:

- ARD / RID class: Not regulated
 - Danger code: Not regulated
 - UN number: Not regulated
 - Hazard label: Not regulated
 - Description of goods: *In vitro* diagnostic test kit
- Inland waterways ADN / ADNR:** Not regulated
- Sea IMDG:** Not regulated
- Air CAO / IATA:** Not regulated

15-Regulatory information

Labeling according to EU guidelines:

Code letter and hazard designation:

TMB substrate/chromogen Product Code # 525700

- Risk phrases R:
 - R36
Irritating to eyes
 - R38
Irritating to skin.
- Safety phrases S:
 - S 26
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 - S 36
Wear suitable protective clothing.
 - S 23
Do not breathe vapor.

Stop Solution Product Code # 915401

- Risk phrases R:
 - R36
Irritating to eyes
 - R38
Irritating to skin.
- Safety phrases S:
 - S1/2
Keep locked up and out of the reach of children
 - S 26
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 - S 36
Wear suitable protective clothing.



TRINITY BIOTECH USA

MATERIAL SAFETY DATA SHEET

MSDS

NAME OF PRODUCT:

Ribosomal TEST KIT
Product Code: 2338770

MSDS Number: 8770-MS

Page 10 of 10

Effective date: Jan 2008

Revision C

S 23
Do not breathe vapor.

Wash Buffer Product Code # 827402

- Risk phrases R:

R36
Irritating to eyes
R38
Irritating to skin.
R40
Possible risk of irreversible effects

- Safety phrases S:

S 26
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 36
Wear suitable protective clothing.
S 23
Do not breathe vapor.

Substance(s) responsible for major health hazards: DMSO, CAS # 67-68-5. Sulfuric Acid, CAS # 7664-93-9. Tween 80, CAS # 9005-65-6.

16-Other information

Recommended use:

This product is an *in vitro* diagnostic testing kit and should only be used according to its package insert instructions.

Others:

The above information is based on data available to Trinity Biotech USA and is believed to be correct. Since the information may be applied under conditions beyond the control of Trinity Biotech USA and with which the company may be unfamiliar, Trinity Biotech USA does not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections, which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.
