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MSDS 012, Ed 3
Effective: Feb 2010
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Material Safety Data Sheet

QuantiFERON[®]-TB Gold ELISA kit

Cat No.: 0594-0201

SECTION 1: COMPANY IDENTIFICATION and PRODUCT GROUP NAME

Company Identification:

Cellestis Inc. 28358 Constellation Rd Unit 698 Valencia, CA, 91355 USA	Cellestis International Pty Ltd Level 1, Office Tower 2 1341 Dandenong Road Chadstone, Victoria, 3148 Australia	Cellestis GmbH Robert Bosch Strasse 7 D-64293 Darmstadt Germany
Tel: +661 775-7480 Fax: +661 775-7479 Toll free: 800 519-4627 www.cellestis.com	Tel: +613 8527 3500 Fax: +613 9568 6623 www.cellestis.com	Tel: +49 6151 428 59-0 Fax: +49 6151 428 59-110 www.cellestis.com

Product Group Name:

QuantiFERON[®]-TB Gold ELISA kit

SECTION 2: HAZARD IDENTIFICATION

If used as intended and handled in a correct manner in accordance to our instructions for use no particular hazards to human health will occur.

In case of fire or extreme heat molten product adheres to the skin and causes burns. Also toxic and dangerous vapors, fumes and combustion products will be liberated and will irritate eyes and respiratory system.

Environmental Hazards: Not classified as dangerous under EU-Criteria.

Other Hazards: Not classified as dangerous for supply or conveyance.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Exposure Limits	Hazard Classification EU Criteria	Weight %
Enzyme Stopping Solution <i>Sulphuric acid</i> ** <i>Water</i>	7664-93-9 7732-18-5	1.0mg/m ³ None known	No classification necessary	1-9 >60
Enzyme Substrate Solution <i>Hydrogen peroxide</i>	7722-84-1	1ppm / 1.4mg/m ³	No classification necessary	<1
Wash Buffer 20X conc. <i>Sodium ethyl mercuric</i>	54-64-8	None known	No classification	0.01

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<i>thiosalicylate</i>			necessary	
Chemical Name	CAS Number	Exposure Limits	Hazard Classification EU Criteria	Weight %
Green Diluent	n.a.*	None known		10-30
<i>Mouse serum</i>				
<i>Casein sodium</i>	9005-46-3	None known	No classification	<10
<i>Sodium ethyl mercuric thiosalicylate</i>	54-64-8	None known	necessary	0.01
Conjugate 100X concentrate. Freeze dried, contains anti-human IFN- γ HRP.				
<i>Casein sodium</i>	9005-46-3	None known	No classification necessary	<5
Human IFN- γ Standard. Freeze dried, contains recombinant human IFN- γ .				
<i>Casein sodium</i>	9005-46-3	None known	No classification necessary	<5
Microplate strips – coated with anti-human IFN- γ antibody	n.a.*	None known	No classification necessary	

*n.a.: Not applicable

**Concentration of Sulphuric acid is 0.5M.

SECTION 4: EMERGENCY AND FIRST AID MEASURES

Not expected to give rise to an acute hazard under normal conditions of use.

SWALLOWED

ENZYME STOPPING SOLUTION

The liquid is highly discomforting to the gastro-intestinal tract and may be harmful if swallowed. Ingestion may result in nausea, abdominal irritation, pain and vomiting.

ENZYME SUBSTRATE SOLUTION

The liquid is discomforting to the gastro-intestinal tract. Ingestion may result in nausea, abdominal irritation, pain and vomiting.

HUMAN IFN- γ STANDARD & CONJUGATE 100X CONCENTRATE

The material may be discomforting to the gastro-intestinal tract.



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EYE

ENZYME STOPPING SOLUTION

If this product comes in contact with the eyes: Immediately hold the eyes open and wash continuously for at least 15 minutes with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Transport to hospital or doctor without delay. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

OTHER KIT COMPONENTS

If product comes into contact with eyes: Wash affected area with water. If irritation continues, seek medical attention.

SKIN

If product comes in contact with the skin: Wash affected areas thoroughly with water (and soap if available). Seek medical attention in event of irritation.

INHALED

If fumes or combustion products are inhaled: Remove to fresh air. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed where possible, prior to initiating first aid procedures. If breathing is shallow or has stopped, ensure clear airway and apply resuscitation, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor.

ADVICE TO DOCTOR

Treat symptomatically.

CHRONIC HEALTH EFFECTS

Principal routes of exposure are by accidental skin and eye contact and by inhalation of vapours, especially at higher temperatures.

FIRST AID

SWALLOWED

If poisoning occurs, contact a doctor or Poisons Information Centre. In Australia phone 13 1126; New Zealand 03 4747000. If swallowed, DO NOT induce vomiting. Give a glass of water.



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SECTION 5: FIRE FIGHTING MEASURES

Flash Point: n.a.

Autoignition Temperature: n.a.

Combustibility: combustible

Suitable extinguish media: Water spray or fog, foam, dry chemical powder, carbon dioxide (CO₂), sand or earth may be used for small fires only.

Unsuitable extinguish media: Water in a jet

Not classified as flammable but will burn.

Combustion trials about development of possible combustion products and their amount under well-defined conditions have not been thoroughly investigated.

Protective Equipment for Fire Fighters: Use full protective clothing for chemicals and a self-contained breathing apparatus operating in positive pressure.

SECTION 6: ACCIDENTIAL RELEASE MEASURES

Personal precautions and protection: In accordance to common hygiene measures wear gloves while handling with plasma samples.

Environmental precautions: No specific measures for used components. Utilize appropriate containment to avoid environmental contamination and ensure subsequent safe disposal.

SECTION 7: HANDLING AND STORAGE

Handling: Only trained personal should use this product. In accordance with legal regulations and common hygiene measures for labs and hospitals, it is recommended to wear gloves while handling this product.

Avoid contact with heated or molten product. Do not breathe fumes or vapors from heated product.

Storage: Keep away from direct sunlight. Keep away from heat. Store between 2°C and 8°C.



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	Enzyme Stopping Solution	Enzyme Substrate Solution	Wash Buffer 20X conc	Green Diluent	Conj 100X conc	Human IFN-γ Std	Microplate Strips
Decomposition Temperature (°C)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Flash Point (°C)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Auto Ignition Temp (°C)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Explosive properties	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable
Oxidizing properties	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Vapour pressure	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable
Density (g/cm ³) 20°C	approx 1.0	approx 1.0	approx 1.1	approx 1.1	not applicable	not applicable	not applicable
Solubility Water solubility (20°C)	miscible	miscible	miscible	miscible	miscible	miscible	not applicable
Oil solubility	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	not applicable
Partition coefficient n-octanol / water	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable
Vapour Density	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Evaporation rate	n.a.	n.a.	n.a.	n.a.	not applicable	not applicable	not applicable
Conductivity	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Viscosity	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

SECTION 10: STABILITY AND REACTIVITY

Conditions to avoid: In case of fire or if ELISA kit is exposed to heat thermal decomposition will take place: toxic, flammable and dangerous vapors, fumes and combustion products may be emitted.

Hazardous decomposition products: Oxides of Carbon.

Materials to avoid / Incompatibilities: None known



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SECTION 11: TOXICOLOGICAL INFORMATION

QuantiFERON[®]-TB Gold ELISA kits are non toxic.

According to experience, the product is considered to be harmless to health if handled in the correct manner.

Acute eye effects: None under normal conditions, fumes or gases from heated or burning product may be irritating.

Inhalation Toxicity: None under normal conditions, fumes or gases from heated or burning product may be irritating.

Acute skin effects: None under normal conditions, sulphuric acid (Stopping Solution) causes severe burns.

Ingestion toxicity: n.a.

Exposure limits: Not established

Reproductive toxicity: Not established

Synergistic products: Not established

Teratogenicity: Not established

Mutagenicity: Not established

Sensitization to product: Not established

Carcinogenicity: Not established

Other chronic effects: None identified

Signs and symptoms of overexposure: None identified

SECTION 12: ECOLOGICAL INFORMATION

No data is available on the adverse effects of this product on environment. This product contains no substance classified as dangerous for the environment.

Expected to be non toxic at limit of water solubility. Not readily biodegradable. The product will persist in the environment as lumps of particles and disperses very slowly. These particles may have physical effects on aquatic and terrestrial organisms.

NEVER DISPOSE OF USED KIT COMPONENTS INTO THE ENVIRONMENT.

SECTION 13: DISPOSAL CONSIDERATIONS

Unused ELISA kits can be disposed in accordance to Regional or National regulations.

Used ELISA kits (specifically the microtitre plates) must be disposed in accordance with Local, State and Federal regulations as hazardous and toxic waste of laboratories and hospitals.



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SECTION 14: TRANSPORT INFORMATION

Non hazardous product, therefore hazard warning labelling and specific safety measures for conveyance are not compulsory.

Not restricted under IATA Regulations – The product is not dangerous and complies with air transport regulations.

SECTION 15: REGULATORY INFORMATION

This Material Safety Data Sheet (MSDS) has been prepared in compliance with the following regulations:

Classification according to EC guidelines: 91/155/EEC, 93/112/EC, 88/379/EC

National Regulations: Chemical (Hazard Information and Packaging) Regulations: ChemG 1996 (Austria).

Occupational Safety and Health Administration (OSHA). CFR 1910.1200 – Hazard Communication, Section (g) “Material Safety Data Sheets”.

Health Canada – Hazardous Products Act. This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information as required by the CPR. (Schedule 1 (s. 12))

National Occupational Health and Safety Commission (NOHSC), Commonwealth of Australia (NOHSC: 2011(2003)). National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd Edition.

Note: This paragraph summaries only the most important legal provisions for the product to be described in the Material Safety Data Sheet. Please note that there may be additional legal provisions to be observed. We recommend that you keep yourself informed about all applicable international, national and local regulations.



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Water Hazard Class: Not assigned

Risk description, safety recommendations and hazard symbols:

- S 15 Keep away from heat.
- S 35 This product must be disposed of in a safe way.
- S 41 In case of fire do not breathe fumes.
- S 42 During fumigation wear suitable respiratory equipment.
- S 47 Keep at temperature not exceeding 8°C.

SECTION 16: OTHER INFORMATION

Only trained personal should handle this product. Wear personal protective equipment as common while handling with human blood samples in accordance to legal regulations and common practiced hygiene measures in labs and hospital. Read instructions for use carefully.

NEVER LET USED ELISA KITS OUTSIDE CONTROLLED AREAS.

To best of our knowledge, the information contained herein is accurate. However, neither Cellestis nor any of its subcontractors assumes any liability what so ever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that this is the entire list of possible endangering that might arise.