

**MATERIALS SAFETY DATA SHEET****1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING**

<u>Product Name:</u>	Human sTNFR1 EIA
<u>Cat Number:</u>	BIO94 / BIO94RUO
<u>Use:</u>	An enzyme immunoassay for the quantitative determination of soluble tumor necrosis factor receptor 1 (sTNFR1) in human serum and plasma.
<u>Company/Undertaking Identification:</u>	EKF Diagnostics Ltd, Unit 9 Trinity Technology and Enterprise Campus, Pearse Street, Dublin 2, Ireland. www.EKFdiagnostics.com Tel: (+353) 1 670 8576 Fax: (+353) 1 670 8575 Email: info@ekfdiagnostics.com

2. COMPOSITION / INFORMATION ON INGREDIENTS:

Reagent	Content
<u>sTNFR1 Microplate:</u>	12 x 8 well strips coated with mouse monoclonal IgG directed against human sTNFR1.
<u>sTNFR1 Calibrator:</u>	2.5ng recombinant human sTNFR1. Contains ProClin 300.
<u>sTNFR1 Control Low:</u>	1.8mL buffered solution of recombinant human sTNFR1. Contains ProClin 950 and Bronidox L.
<u>sTNFR1 Control High:</u>	1.8mL buffered solution of recombinant human sTNFR1. Contains ProClin 950 and Bronidox L.
<u>Assay Diluent:</u>	6mL buffered protein solution. Contains ProClin 300.
<u>Sample Diluent:</u>	2 x 21mL buffered animal serum. Contains ProClin 300 and Sodium Azide.
<u>Wash Buffer:</u>	21mL of 25-fold concentrated buffered surfactant solution. Contains ProClin 300.
<u>sTNFR1 Conjugate:</u>	21mL solution of anti-human sTNFR1 polyclonal antibody conjugated to horseradish peroxidase. Contains ProClin 300.
<u>Substrate Solution A:</u>	12mL solution of stabilised Hydrogen Peroxide.
<u>Substrate Solution B:</u>	12mL solution of stabilised 5,5',3,3' - Tetramethylbenzidine (TMB).
<u>Stop Solution:</u>	6mL solution of 2N Sulfuric Acid (1M).

**MATERIALS SAFETY DATA SHEET****3. HAZARDS IDENTIFICATION:**

The following safety data sheet identifies the potential hazards related to use of the Human sTNFR1 EIA kit. Hazardous ingredients used in the manufacture of the kit components listed in section 2 are outlined below. These materials are known to be hazardous in their concentrated form; however they are present in a diluted form in the final kit component formulation and therefore the risk of harm being caused by certain hazardous ingredients may be reduced compared to the concentrated ingredient. Nevertheless, the hazards are still present and users should handle the product with care accordingly. Stop solution provided with this kit contains sulfuric acid at a final concentration of 1M, which is classified as an irritant. The applicable chemical classification and associated risk (R) and safety (S) phrases are defined in section 16.

This safety data sheet should be used as a guide only and does not represent an all-inclusive study of all hazards associated with the product.

Chemical	Nature of Hazard	Classification
Sulfuric Acid	Corrosive, Irritant	C, Xi, R35, S26-30-45
3,3',5,5' - Tetramethylbenzidine (TMB)	Irritant	Xi, R36-37-38, S26-36
Sodium Azide	Very Toxic, Dangerous for the Environment	T+, N, R28-32, S28-45-60-61
5-Bromo-5-nitro-1,3-dioxane (Bronidox L)	Harmful	Xn, R22-38, S36
ProClin 300	Corrosive, Dangerous for the Environment	C, N, R20/21/22-34-43-51/53, S26-36/37/39-45-61
ProClin 950	Corrosive	C, R32-43, S26-36/37/39-45

4. FIRST AID MEASURES:

After inhalation: If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

After skin contact: Wash skin with copious amounts of water. Remove contaminated clothing and shoes.

After eye contact: Flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids. If any irritation persists, obtain medical assistance.

After ingestion: Wash out mouth with copious amounts of water. Give plenty of water to drink. Obtain medical assistance if large quantity is ingested.

**MATERIALS SAFETY DATA SHEET****5. FIRE FIGHTING MEASURES:**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Some components may decompose and emit toxic fumes under fire conditions (TMB, Bronidox L, ProClin 300, ProClin 950).

6. ACCIDENTAL RELEASE MEASURES:

Methods for cleaning up: Wipe up spills with absorbent paper, then clean area with a concentrated chlorine solution (0.5% hypochlorite) and copious amounts of water. Discard all materials used to wipe up spills using biohazard waste facilities. Residues of chemicals, preparations and kit components are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

7. HANDLING AND STORAGE:

Handling All kit components and clinical specimens should be handled as though potentially biohazardous.

Storage: Store all reagents and ELISA plate at 2-8°C.

Specific Use: This product is for laboratory use only.

8. EXPOSURE CONTROLS:

All patient specimens are considered potentially biohazardous materials. They should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual "Biosafety in Microbiological and Biomedical Laboratories", 1998.

Some of the reagents in this kit contain toxic or irritant components (Refer to section 3). Wear protective clothing, disposable latex gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Not Applicable

10. STABILITY AND REACTIVITY:

Sulfuric acid is incompatible with water and bases.

TMB (3,3',5,5' – Tetramethylbenzidine) is incompatible with metals, strong acids and strong oxidizing agents. Avoid exposure to light.

Sodium Azide may cause explosion and/or toxic gas formation when exposed to lead and copper plumbing. Avoid sources of strong heat.

Bronidox L (5-Bromo-5-nitro-1,3-dioxane) is incompatible with strong oxidising agents.

ProClin 300 and **ProClin 950** are incompatible with strong oxidising agents, amines, mercaptans and reducing agents.

**MATERIALS SAFETY DATA SHEET****11. TOXICOLOGICAL INFORMATION:**

TMB (3,3',5,5' – Tetramethylbenzidine) may be harmful if inhaled, swallowed or by adsorption through skin.

Sodium Azide is toxic by inhalation, in contact with eyes/skin and/or if swallowed.

Bronidox L (5-Bromo-5-nitro-1,3-dioxane) may be harmful if inhaled, swallowed or by adsorption through skin.

ProClin 300 is harmful if inhaled and is extremely destructive to the tissue of the mucous membranes and upper respiratory tract. Harmful if swallowed and if adsorbed through skin and eyes, causes burns. May provoke asthmatic responses in persons with asthma who are sensitive to airway irritants.

ProcClin 950 is toxic if inhaled and is extremely destructive to the tissue of the mucous membranes and upper respiratory tract. Harmful if swallowed and if adsorbed through skin and eyes, causes burns.

12. ECOLOGICAL INFORMATION:

Sulfuric acid is harmful to aquatic life in very low concentrations. It may be dangerous if it enters water intakes. Do not allow to enter waters, waste water or soil.

Sodium azide is highly toxic for aquatic organisms and may cause long-term adverse effects in the aquatic environment. Do not allow to enter waters, waste water or soil.

ProClin 300 and **ProClin 950** are very toxic to aquatic life; avoid emptying into waters or drains.

13. DISPOSAL / CONSIDERATIONS:

Dispose of all clinical specimens, infected or potentially infected material in accordance with good laboratory practice. All such material should be handled and disposed of as if potentially infectious. Residues of chemicals, preparations and kit components are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

14. TRANSPORT INFORMATION:

This manufactured product is not subject to International Air Transport Association Dangerous Goods Regulations.

15. REGULATORY INFORMATION AND CONSIDERATIONS:

European Union Directive 67/548/EEC

European Union Directive 1999/45/EC

EU Regulation 1907/2006

Local Waste Disposal Regulations

Directive 98/79/EC on *in vitro* diagnostic medical devices

**MATERIALS SAFETY DATA SHEET****16. OTHER INFORMATION:**

Training: This product should only be handled by individuals technically qualified in handling potentially biohazardous material. The contents of this MSDS should be known before use.

Definitions of chemical classification and associated risk (R) and safety (S) phrases listed in section 3:

Classification

C	Corrosive
N	Dangerous for the environment
T+	Very toxic
Xi	Irritant
Xn	Harmful

Risk Phrases

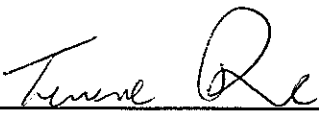
R20	Harmful by inhalation
R22	Harmful if swallowed
R34	Causes burns
R35	Causes severe burns
R36/37/38	Irritating to eyes, respiratory system and skin
R37	Irritating to the respiratory system
R38	Irritating to the skin
R43	May cause sensitization by skin contact
R50	Very toxic to aquatic organisms

Safety Phrases

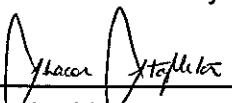
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S30	Never add water to this product
S36	Wear suitable protective clothing
S37	Wear suitable gloves
S39	Wear eye/face protection
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
S45	In case of accident or if you feel unwell, seek medical advice immediately (show label where possible)
S61	Avoid release to the environment. Refer to special instructions safety data sheet.



MATERIALS SAFETY DATA SHEET

Approved: 
 Health and Safety Officer

Date: 27/09/2013

Approved: 
 Senior Management Team Member

Date: 30/09/2013

Amendment History			
From Issue	To Issue	Issue Date	Change Control Form # (DOC/1/RS(A))
N/A	0	27/09/2013	13-038