

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

Product Name: IMUBIND® ADAMTS13 Autoantibody ELISA
 Product No.: 814, 814RUO
 Configuration: 96 well ELISA, 6 strips each of 16 wells (each strip equals 2 columns x 8 rows)
 Use of Product: Measurement of IgG antibodies to ADAMTS13 protein in human plasma
 Manufacturer: Sekisui Diagnostics, LLC
 500 West Avenue
 Stamford, CT 06902 USA
 Tel: (203) 602 7777
 Fax: (203) 602 2221

2. COMPOSITION/INFORMATION ON INGREDIENTS

Reagent/Component	Chemical Name	CAS Number	Percent	LD ₅₀
ADAMTS13 Coated Microwells	Recombinant Human ADAMTS13 SiO ₂ (silica gel desiccant packet)	N/A N/A	N/A N/A	N/A Do Not Ingest
Plasma Standard	Human Plasma Sodium Citrate Bovine Serum Albumin Gentamicin Sulfate	9001-26-7 68-04-02 9048-46-8 1405-41-0	10% 3.0% 0.6% 0.05%	N/A rat, i.p. – 1548 mg/kg N/A N/A
Positive Control	Human Plasma Sodium Citrate Bovine Serum Albumin Gentamicin Sulfate	9001-26-7 68-04-02 9048-46-8 1405-41-0	10% 3.0% 0.6% 0.05%	N/A rat, i.p. – 1548 mg/kg N/A N/A
Detection Antibody	Goat Anti-Human ADAMTS13 IgG Disodium Phosphate Sodium Chloride Bovine Serum Albumin Peroxidase Type XII (from horseradish) Methylisothiazolone	N/A 7558-79-4 7647-14-5 N/A 9003-99-0 2682-20-4	 1% 0.9% 0.2% N/A 0.02%	N/A rat, oral – 12.9 g/kg rat, oral - 3000 mg/kg N/A N/A N/A
Assay Buffer	Sodium Citrate Bovine Serum Albumin Gentamicin Sulfate	68-04-02 9048-46-8 1405-41-0	3.0% 0.6% 0.05%	rat, i.p. – 1548 mg/kg N/A N/A
Substrate	TMB (3,3',5,5'-tetramethylbenzidine)	54827-93-9	< 0.02%	N/A
Wash Buffer	Disodium Phosphate Sodium Chloride Potassium Chloride Tween 20	7558-79-4 7647-14-5 7447-40-7 9005-64-5	1% 0.8% 0.02% 0.05%	rat, oral – 12.9 g/kg rat, oral - 3000 mg/kg rat, oral – 36700 µL/kg rat, oral – 40.55 g/kg

3. HAZARDS IDENTIFICATION

Potential Health Hazards

Eye Exposure:	May be harmful by eye exposure.
Dermal Exposure:	May be harmful if absorbed through the skin.
Oral Exposure:	May be harmful if swallowed.
Inhalation Exposure:	May be harmful if inhaled. Irritating to mucous membranes and the upper respiratory tract.

4. FIRST AID MEASURES

Eye Exposure:	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek medical attention.
Dermal Exposure:	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing.
Oral Exposure:	If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.
Inhalation Exposure:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen.

5. FIRE FIGHTING MEASURES

Flammability:	Solutions are non-flammable. Boxing, instruction papers and powdered reagents are flammable.
Extinguishing Media:	Use extinguishing media appropriate to the surrounding fire conditions, such as carbon dioxide, dry chemical powder or foam.
Fire Fighting Instructions:	Wear self-contained breathing apparatus and protective clothing appropriate for fighting a fire involving chemical materials to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. In case of skin contact, flush with copious amounts of water and remove contaminated clothing.
Methods For Cleaning Up:	Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete. Do not empty into drains.

7. HANDLING AND STORAGE

Handling:	Avoid inhalation. Avoid contact with eyes, skin and clothing.
Storage:	The product is stable until the expiration date stated on its labeling when stored at 2°-8°C.
Safety:	<p>The source material for the plasma/serum based reagent(s) has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human blood will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen.</p> <p>The source material for reagents prepared from bovine plasma was collected from animals free from BSE and tested for the absence of infectious agents. As no known test method can provide</p>

complete assurance that products derived from animal blood will not transmit blood-borne pathogens, these reagents should be handled as recommended for any potentially infectious specimen.

The source material for reagents prepared from animal sera was collected from healthy animals and tested for the absence of infectious agents. As no known test method can provide complete assurance that products derived from animal blood will not transmit blood-borne pathogens, these reagents should be handled as recommended for any potentially infectious specimen.

Hygienic Practice: Wash hands with soap and water following use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye/Face Protection: Chemical safety goggles.

Hand Protection: Compatible chemical resistant gloves.

Respiratory Protection: NIOSH (USA) or CEN (EU) approved respirator. Mechanical exhaust required.

Skin Protection: Compatible chemical resistant gloves and other protective clothing as required to prevent skin contact.

General Hygiene Practices: Wash promptly if skin comes into contact with product. Wash thoroughly after handling. Remove any clothing that comes into contact with the product. Do not smoke or eat in the work environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	ADAMTS13 Microwells	Plasma Standard	Positive Control	Detection Antibody	Assay Buffer	TMB Substrate	Wash Buffer
Appearance	N/A	straw-colored, lyophilized powder	straw-colored, lyophilized powder	clear, pale-yellow liquid	white, lyophilized powder	clear liquid	powder
Odor	N/A	N/A	N/A	N/A	N/A	N/A	N/A
pH	N/A	N/A	N/A	6.0-7.0	N/A	N/A	7.4
Freezing Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vapor Pressure	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Specific Gravity	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Solubility	N/A	water soluble	water soluble	N/A	water soluble	N/A	water soluble
Evaporation Rate	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
Surface Tension	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Boiling Point	N/A	N/A	N/A	100°C	N/A	N/A	N/A
Melting Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flash Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Lower Explosive Limit	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Upper Explosive Limit	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Autoignition Temp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A

N/A = not available

10. STABILITY AND REACTIVITY

Stability:	Stable.
Incompatible Materials:	Strong oxidizing reagents.
Hazardous Decomposition Products:	carbon monoxide, carbon dioxide, nitrogen oxides.
Hazardous Polymerization:	Does not occur.

11. TOXICOLOGICAL INFORMATION

Toxicity Data : See Section 2

The health effects noted above are based on the extrapolation of data on the pure product ingredients. To the best of our knowledge, no health effects have been identified for the product mixture under normal conditions of use, although the health effects of the product have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Use in accordance with good laboratory practices. Do not waste into the environment. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. DISPOSAL CONSIDERATIONS

Contact a licensed professional waste disposal service to dispose of this material. Disposal should be made in accordance with existing disposal practices employed for infectious waste at your institution. Observe all federal, state and local environmental regulations and laws.

This product is classified as harmful.

Reference: Italian Legislative Decree 152/2006 and the following modifications.
Decision 2000/532/EC of May 3, 2000 and modifications.

14. TRANSPORT INFORMATION

DOT:	Proper Name For Shipping:	Non-hazardous for air transport
IATA/ICAO	Proper Name For Shipping:	Non-hazardous for air transport
ADR (road):	Proper Name For Shipping:	Non-hazardous for air transport
RID (rail):	Proper Name For Shipping:	Non-hazardous for air transport

15. REGULATORY INFORMATION

This product is classified and labeled in accordance with Directive 1999/45/EC and the following modifications. The health hazard classification has been determined based upon the composition and hazard data of each ingredient. Physical and health hazard information on the reagent mixture has not been determined. Any physical and health hazard information noted is based on a) evaluation of data of the pure ingredient and b) the concentration of each ingredient.

OSHA Hazard: Mild skin irritant, Mild eye irritant

Hazard Classification

EC Symbol:	Xi
Indication of Danger:	Irritant.
Risk Code:	36/37/38
Safety Code:	26-36

US Classification

Indication of Danger:	Irritant.
Risk Statement:	Irritating to eyes, respiratory system and skin.
Safety Statements:	In case of contact with eyes, rinse immediately with plenty of water and seek medical attention. Wear suitable protective clothing.

United States Regulatory Information

SARA Listed: No

Canada Regulatory Information

DSL: No
NDSL: No

16. OTHER INFORMATION

This Material Safety Data Sheet has been drawn in accordance with Directive 2001/58/EC.

The information supplied in this Material Safety Data Sheet represents the data and best information available on the date of preparation. It is provided to allow for the proper and safe use, storage, transport and disposal of the product. It is not to be considered as a warranty, guarantee or specification of the product quality. It is related to the materials specifically indicated and does not apply if these are used in combination with other materials or during processes not indicated in the text of this safety data sheet.

Sekisui Diagnostics, LLC shall not be held liable for any damage resulting from handling or from contact with the above product.