

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: IMUBIND® vWF Activity ELISA

1.2 Product REF: 885

1.3 Configuration: ELISA, 96 well

1.4 Use of Product: For Research Use Only.

1.5 Company **Manufacturer:** Sekisui Diagnostics, LLC
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 Stamford, CT 06902 USA
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2. HAZARDS IDENTIFICATION

2.1 Classification: Toxic, Danger

2.2 Potential Health and Environmental Effects

Skin Exposure: Corrosive and destructive to tissue.

Eye Exposure: May cause severe eye irritation.

Inhalation Exposure: May cause respiratory irritation.

Ingestion: Toxic if swallowed.

Environmental Exposure: Might cause adverse effects to the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Reagent/Component	Chemical Name	CAS Number	EINECS No.	Concentration, w/v, %
Anti-Human vWF IgG Coated Microwells	Anti-Human vWF IgG SiO ₂ (silica gel desiccant packet)	NA 112926-00-8	NA 231-545-4	NA NA
Calibrator	Normal Human Plasma	NA	NA	100%
vWF Control 1 (Normal)	Normal Human Plasma	NA	NA	100%
vWF Control 2 (Normal)	Normal Human Plasma	NA	NA	100%
vWF Conjugate	Anti-Human vWF IgG Disodium Phosphate Sodium Chloride Bovine Serum Albumin Peroxidase Type XII (from horseradish)	NA 7558-79-4 7647-14-5 9048-46-8 9003-99-0	NA 231-448-7 231-598-3 232-936-2 232-668-6	NA 1.0% 0.9% 1.0% NA

Sample Diluent Concentrate	Sodium Phosphate Dibasic	7558-79-4	231-448-7	0.64%
	Sodium Phosphate Monobasic	13472-35-0	231-449-2	0.07%
	Sodium Chloride	7647-14-5	231-598-3	4.25%
	Bovine Serum Albumin	9048-46-8	232-936-2	0.5%
	Bronopol	52-51-7	200-143-0	0.1%
	Tween 20	9005-64-5	NA	1.0%
	Amaranth Dye	915-67-3	213-022-2	0.035%
Substrate	TMB (3,3',5,5'-tetramethylbenzidine)	54827-17-7	259-364-6	NA
Wash Buffer Concentrate	Boric Acid	10043-35-3	233-139-2	1.0%
	Disodium Tetraborate	1330-43-4	215-540-4	0.47%
	Sodium Chloride	7647-14-5	231-598-3	14%
	Bronopol	52-51-7	200-143-0	0.32%
	Triton X-1000	9002-93-1	NA	1.7%
Stop Solution	Sulfuric Acid	7664-93-9	231-639-5	9.8%

NA – Not Available

4. FIRST AID MEASURES

- Skin Exposure:** In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing. Seek medical attention if adverse symptoms appear.
- 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 if adverse symptoms appear.
- Inhalation Exposure:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen and seek medical attention.
- Ingestion:** If swallowed, wash out mouth with water provided person is conscious. Seek immediate medical attention.

5. FIRE FIGHTING MEASURES

- Flammability:** Solutions are non-flammable. Boxing, instruction papers and powdered reagents are flammable.
- Suitable Extinguishing Media:** Use extinguishing media appropriate to the surrounding fire conditions, such as carbon dioxide, dry chemical powder, foam or water spray.
- Equipment for fire fighting:** 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.
- Environmental Precautions:** Do not let the product enter the drainage system.
- Methods For Cleaning Up:** Sweep up dry product, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

7. HANDLING AND STORAGE

7.1 Handling

Handling Procedure:	Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged exposure. Provide adequate ventilation in all work areas.
Safety:	This product contains human source material that 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 specimens 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. This product contains animal source material. As no known test method can provide complete assurance that products derived from animal specimens will not transmit blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen.
Hygienic Practice:	Wash hands with soap and water following use.

7.2 Storage

Container:	Keep container tightly closed and labeled with the name of the product.
Recommended Temperature:	2°-8°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure Limit Values

TLV/TWA:	6 mg/m ³ for Silica Gel per OSHA
TLV/TWA:	2 mg/m ³ for Boric Acid per ACGIH
TLV/TWA:	2 mg/m ³ for Disodium Tetraborate per ACGIH
TLV/TWA:	0.2 mg/m ³ for Sulfuric Acid per ACGIH
OELV/TWA:	10 mg/m ³ for Disodium Tetraborate per OSHA
OELV/TWA:	1 mg/m ³ for Sulfuric Acid per OSHA
TLV/STEL:	6 mg/m ³ for Boric Acid per ACGIH
TLV/STEL:	6 mg/m ³ for Disodium Tetraborate per ACGIH
TWA:	1 mg/m ³ for Disodium Tetraborate per NIOSH

8.2 Personal Protection

Respiratory Protection:	Respirator protection is not required. Where protection is desired, use type N95 (US) or type P1 (EN 143) dust masks or. For higher level protection, use NIOSH (USA) or CEN (EU) approved respirators and filters.
Eye Protection:	Chemical safety goggles.
Hand Protection:	Compatible chemical resistant gloves. Use proper glove removal technique to avoid skin contact. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.
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	Anti-Human vWF IgG Coated Microwells	Calibrator	vWF Control 1 (Normal)	vWF Control 2 (Abnormal)	vWF Conjugate	Sample Diluent Concentrate	Substrate	Wash Buffer Concentrate	Stop Solution
Appearance	N/A	straw-colored powder	straw-colored powder	straw-colored powder	blue liquid	red liquid	clear liquid	clear liquid	clear liquid
Odor	N/A	N/A	N/A	N/A	none	none	none	none	Yes
pH	N/A	N/A	N/A	N/A	N/A	7.4	N/A	7.4	
Freezing Point	N/A	N/A	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	N/A	N/A
Specific Gravity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Water Solubility	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes, in all proportions
Evaporation Rate	N/A	N/A	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	N/A	N/A
Surface Tension	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Boiling Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Melting Point	N/A	N/A	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	N/A	N/A
Lower Explosive Limit	N/A	N/A	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	N/A	N/A
Flammability	N/A	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A
Autoignition Temperature	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

N/A = not available

10. STABILITY AND REACTIVITY

- 10.1 Stability:** The product is stable until the expiration date stated on its label when properly stored at 2°-8°C.
- 10.2 Conditions To Avoid:** Keep away from heat.
- 10.3 Materials To Avoid:** Strong acids, strong reducing agents, strong oxidizing reagents.
- 10.4 Hazardous Decomposition Products:** Hazardous decomposition products due to combustion may include carbon monoxide, carbon dioxide, and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD ₅₀	Inhalation LC ₅₀	Dermal LD ₅₀
Anti-Human vWF IgG Coated Microwells	Anti-Human vWF IgG SiO ₂ (silica gel desiccant packet)	No Data Available No Data Available	No Data Available No Data Available	No Data Available No Data Available
Calibrator	Normal Human Plasma	No Data Available	No Data Available	No Data Available
vWF Control 1 (Normal)	Normal Human Plasma	No Data Available	No Data Available	No Data Available
vWF Control 2 (Normal)	Normal Human Plasma	No Data Available	No Data Available	No Data Available
vWF Conjugate	Anti-Human vWF IgG Disodium Phosphate Sodium Chloride Bovine Serum Albumin Peroxidase Type XII (from horseradish)	No Data Available No Data Available No Data Available No Data Available No Data Available	No Data Available No Data Available rat, 1 hr >42,000 mg/m ³ No Data Available No Data Available	No Data Available No Data Available rabbit, >10,000 mg/kg No Data Available No Data Available
Sample Diluent Concentrate	Sodium Phosphate Dibasic Sodium Phosphate Monobasic Sodium Chloride Bovine Serum Albumin Bronopol Tween 20 Amaranth Dye	No Data Available No Data Available No Data Available No Data Available rat, 180 mg/kg rat, 40,554 mg/kg No Data Available	No Data Available No Data Available rat, 1 hr >42,000 mg/m ³ No Data Available rat, 6 hr >5,000 mg/m ³ No Data Available No Data Available	No Data Available No Data Available rabbit, >10,000 mg/kg No Data Available rat, 1,600 mg/kg No Data Available No Data Available
Substrate	TMB (3,3',5,5'- tetramethylbenzidine)	No Data Available	No Data Available	No Data Available
Wash Buffer Concentrate	Boric Acid Disodium Tetraborate Sodium Chloride Bronopol Triton X-1000	rat, 2,660 mg/kg rat, 2,600 mg/kg No Data Available rat, 180 mg/kg rat, 1,800 mg/kg	No Data Available No Data Available rat, 1 hr >42,000 mg/m ³ rat, 6 hr >5,000 mg/m ³ No Data Available	No Data Available rabbit, >2,000 mg/kg rabbit, >10,000 mg/kg rat, 1,600 mg/kg rabbit, 8,000 mg/kg
Stop Solution	Sulfuric Acid	rat, 2,140 mg/kg	rat, 2 hr, 510 mg/m ³	No Data Available

11.2 Irritation

Skin: Corrosive and destructive to tissue (due to Sulfuric Acid)
 Skin irritation in rabbit (due to Bronopol)
 Mild skin irritation in rabbit in 24 hours (due to Disodium Phosphate)
 Mild skin irritation in human in 3 days (due to Tween 20)

Eye: Severe eye irritation in rabbit (due to Sulfuric Acid)
 Mild eye irritation in rabbit in 24 hours (due to Disodium Phosphate)

Inhalation: May cause respiratory irritation (due to Bronopol) No Data Available

11.3 Sensitization

Skin: May cause an allergic skin reaction (due to Bronopol). No Data Available.

Inhalation: May cause an allergic respiratory reaction. No Data Available.

11.4 Carcinogenicity

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen.

11.5 Mutagenicity

No data available

11.6 Teratogenicity

Fetotoxicity. Presumed human reproductive toxicant (due to Boric Acid, Sodium Tetraborate).

For the other components of this product, 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

12.1 Toxicity:

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.

Toxicity to fish (Boric Acid)	LC50, <i>Ptychocheilus lucius</i> – 289 mg/L, 96 hours
Toxicity to fish (Boric Acid)	LC50, <i>Lepomis macrochirus</i> (Bluegill) – > 1,021 mg/L, 96 hours
Toxicity to fish (Bronopol)	LC50, <i>Oncorhynchus mykiss</i> (Rainbow Trout) – 20 mg/L, 96 hours
Toxicity to fish (Sodium Tetraborate)	LC50, other fish – 74 mg/L, 96 hours
Toxicity to fish (Sulfuric Acid)	LC50, <i>Gambusia affinis</i> (Mosquito fish) – 42 mg/L, 96 hours
Toxicity to fish (Tween 20)	LC50, other fish – 350 mg/L, 24 hours
Toxicity to daphnia (Boric Acid)	LC50, <i>Daphnia magna</i> (water flea) – 53.2 mg/L, 21 days
Toxicity to daphnia (Boric Acid)	EC50, <i>Daphnia magna</i> (water flea) – 133 mg/L, 48 hours
Toxicity to daphnia (Bronopol)	EC50, <i>Daphnia magna</i> (water flea) – 1.6 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	NOEC, <i>Daphnia</i> – 1,500 mg/L, 7 days
Toxicity to daphnia (Sodium Chloride)	EC50, <i>Daphnia magna</i> (water flea) – 1,661 mg/L, 48 hours
Toxicity to daphnia (Triton X-100)	EC50, <i>Daphnia</i> – 26 mg/L, 48 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability:

Biodegradability - Triton X-100 - Biotic/Aerobic biochemical oxygen demand – Result 36% not readily biodegradable.

12.4 Bioaccumulative potential: No Data Available

12.5 PBT assessment: No Data Available

12.6 Other adverse effects: Due to Triton X-100, Chemical Oxygen Demand (COD) – 2.19 mg/g

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.

14. TRANSPORT INFORMATION

DOT (US):	Proper Name For Shipping:	Environmentally hazardous substance, liquid, n.o.s, Sulfuric Acid
	UN Number:	1830
	Hazard Class:	8
	Reportable Quantity:	1000 lbs.
	Packing Group:	II
	Marine Pollutant:	No
	Poison Inhalation Hazard:	No
IATA:	Proper name For Shipping:	Environmentally hazardous substance, liquid, n.o.s, Sulfuric Acid
	UN Number:	1830
	Hazard Class:	8
	Packing Group:	II
IMDG:	Proper name For Shipping:	Environmentally hazardous substance, liquid, n.o.s, Sulfuric Acid
	UN Number:	1830
	Hazard Class:	8
	Packing Group:	II
	Marine Pollutant	No

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.

Hazard Classification

EC Symbol:	T
Indication of Danger:	Danger
Risk Code:	R20/22, R36/37/38, R51/53
Safety Code:	S15, S16, S24/25, S26, S36/37/39, S46
Hazard Code:	H242, H301, H303, H313, H314, H315, H316, H317, H318, H319, H333, H335, H360, H400, H402

OSHA Hazards: Corrosive (due to Sulfuric Acid)
 Skin sensitizer, Respiratory sensitizer, Toxic by ingestion (due to Bronopol)
 Harmful by Ingestion, Irritant (due to Triton X-100)
 Teratogen, Reproductive hazard (due to Boric Acid, Sodium Tetraborate)

SARA 302 Components: Sulfuric Acid is subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: Sulfuric Acid is subject to the reporting requirements of SARA Title III, Section 313. This product does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels by SARA Title III, Section 313.

SARA 311/312 Hazards: Acute Health Hazard (due to Amarynth Dye, Bronopol, Sulfuric Acid, Triton X-100)
 Chronic Health Hazard (due to Boric Acid, Silica Gel, Sodium Tetraborate, Sulfuric Acid)
 Fire Hazard (due to Bronopol)

California Prop 65 Components: This product contains a chemical known to the State of California to cause cancer, birth defects or any other reproductive harm.
 Sulfuric Acid

16. OTHER INFORMATION

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 and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.