

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: IMUBIND® Factor VIII ELISA

1.2 Product REF: 884CON

1.3 Configuration: ELISA, 96 well

1.4 Use of Product: For Research Use Only.

1.5 Company

<p>Manufacturer: Sekisui Diagnostics, LLC 500 West Avenue Stamford, CT 06902 USA Tel: (203) 602 7777 Fax: (203) 602 2221 Email: linus@amdiag.com</p>	<p>Distributor EU: American Diagnostica GmbH Kaplangeisse 35 Pfungstadt 64319 Germany Tel: +49 6157 990899 Fax: +49 6157 990808 Email: info@amdiag.de</p>
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2. HAZARDS IDENTIFICATION

2.1 Classification: Xi, Irritant, Warning

2.2 Potential Health and Environmental Effects

Skin Exposure: May be harmful.
Eye Exposure: May be harmful.
Inhalation Exposure: May be harmful.
Ingestion: May be harmful.
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 FVIII IgG Coated Microwells	Anti-Human Factor VIII IgG	NA	NA	NA
	SiO ₂ (silica gel desiccant packet)	112926-00-8	231-545-4	NA
Human FVIII Standard	Human Factor VIII	NA	NA	< 0.001%
	Disodium Phosphate	7558-79-4	231-448-7	0.14%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Tween 20	9005-64-5	NA	0.05%
	Bovine Serum Albumin	9048-46-8	232-936-2	1.0%
	Gentamicin Sulfate	1405-41-0	215-778-9	0.01%
Detection Antibody	Anti-Human FVII IgG	N/A	NA	< 0.001%
	Disodium Phosphate	7558-79-4	231-448-7	0.14%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Peroxidase Type XII (from horseradish)	9003-99-0	232-668-6	NA
Assay Diluent	Disodium Phosphate	7558-79-4	231-448-7	0.14%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Tween 20	9005-64-5	NA	0.05%
	Bovine Serum Albumin	9048-46-8	232-936-2	3.0%
	Gentamicin Sulfate	1405-41-0	215-778-9	0.01%

Substrate	TMB (3,3',5,5'-tetramethylbenzidine)	54827-17-7	259-364-6	NA
Wash Buffer	Disodium Phosphate	7558-79-4	231-448-7	0.14%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Tween 20	9005-64-5	NA	0.05%

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

This product contains no substances with occupational exposure limit values.

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-FVIII IgG Coated Microwells	FVIII Standard	Detection Antibody	Assay Diluent	Substrate	Wash Buffer
Appearance	N/A	white powder	clear liquid	white powder	clear liquid	powder
Odor	N/A	N/A	N/A	N/A	N/A	N/A
pH	N/A	7.4	N/A	7.2	N/A	7.4
Freezing Point	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
Specific Gravity	N/A	N/A	N/A	N/A	N/A	N/A
Solubility	N/A	water soluble	water soluble	water soluble	NA	water soluble
Evaporation Rate	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
Surface Tension	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
Melting Point	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
Lower Explosive Limit	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
Flammability	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

NA = 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-FVIII Antibody Coated Microwells	Anti-Human Thrombomodulin 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
FVIII Standard	Human Factor VIII Disodium Phosphate Sodium Chloride Tween 20 Bovine Serum Albumin Gentamicin Sulfate	No Data Available No Data Available No Data Available rat, oral – 40,554 mg/kg 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 No Data Available rabbit, >10,000 mg/kg No Data Available No Data Available No Data Available
Detection Antibody	Anti-Human Factor VIII IgG Disodium Phosphate Sodium Chloride Peroxidase Type XII (from horseradish)	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 rabbit, >10,000 mg/kg No Data Available
Assay Diluent	Disodium Phosphate Sodium Chloride Tween 20 Bovine Serum Albumin Gentamicin Sulfate	No Data Available No Data Available rat, oral – 40,554 mg/kg 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 No Data Available
Substrate	TMB (3,3',5,5'- tetramethylbenzidine)	No Data Available	No Data Available	No Data Available
Wash Buffer	Disodium Phosphate Sodium Chloride Tween 20	No Data Available No Data Available rat, oral – 40,554 mg/kg	No Data Available rat, 1 hr >42,000 mg/m ³ No Data Available	No Data Available rabbit, >10,000 mg/kg No Data Available

11.2 Irritation

Skin: 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: Mild eye irritation in rabbit in 24 hours (due to Disodium Phosphate).

Inhalation: No Data Available

11.3 Sensitization

Skin: May cause an allergic skin reaction. 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

No data available

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 (Tween 20)	LC50, other fish – 350 mg/L, 24 hours
Toxicity to daphnia (Sodium Chloride)	NOEC, Daphnia – 1,500 mg/L, 7 days
Toxicity to daphnia (Sodium Chloride)	EC50, Daphnia magna (water flea) – 1,661 mg/L, 48 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability No Data Available

12.4 Bioaccumulative potential: No Data Available

12.5 PBT assessment: No Data Available

12.6 Other adverse effects: No Data Available

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 substances, n.o.s (Disodium hydrogenorthophosphate)
UN Number: 3077
Hazard Class: 9
Reportable Quantity: 5000 lbs.
Packing Group: III
Marine Pollutant: No
Poison Inhalation Hazard: No

IATA: Not classified as dangerous goods

IMDG: Not classified as dangerous goods

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: Warning
Risk Code: R20/22, R36/37/38
Safety Code: S24/25, S26, S36/37/39, S46
Hazard Code: H303, H315, H316, H317, H319, H334, H335

OSHA Hazards: Skin sensitizer, Respiratory sensitizer (due to Gentamicin Sulfate)

SARA 302 Components: No chemicals in this product are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: 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 Gentamicin Sulfate).

California Prop 65 Components: This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.

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.