

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: IMUBIND® tPA ELISA
1.2 Product REF: 860
1.3 Configuration: ELISA, 96 well
1.4 Use of Product: For In Vitro Diagnostic Use
1.5 Company

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

2.1 Classification: Toxic, Biohazard, Irritant, Warning
2.2 Potential Health and Environmental Effects

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|-------------------------|--------------------------------------------------------------------------------------------------|
| Skin Exposure: | Causes skin damage. |
| Eye Exposure: | Causes serious eye damage, eye irritation. |
| Inhalation Exposure: | Harmful if inhaled. Carcinogen |
| Ingestion: | Toxic if swallowed. |
| Environmental Exposure: | Might cause adverse effects to the environment. Toxic to aquatic life with long lasting effects. |

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Reagent/Component | Chemical Name | CAS Number | EINECS No. | Concentration, w/v, % |
|------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------------|----------------------------------|
| R1 Anti-Human tPA IgG Coated Microwells | Anti-Human tPA IgG SiO ₂ (silica gel desiccant packet) | NA 112926-00-8 | NA 231-545-4 | NA NA |
| R2 PET Buffer | Disodium Phosphate Sodium Chloride Trisodium EDTA Tween 20 | 7558-79-4 7647-14-5 85715-60-2 9005-64-5 | 231-448-7 231-598-3 205-758-8 NA | 0.14% 0.82% 0.17% 0.05% |
| R3 tPA Standard, 30 ng/mL | Human tPA Human Plasma | NA NA | NA NA | < 0.001% 100% |
| R4 tPA Standard, 0 ng/mL | Human Plasma | NA | NA | 100% |
| R5 Detection Antibody | Anti-Human tPA IgG Peroxidase Type XII (from horseradish) Methylisothiazone | NA 9003-99-0 2682-20-4 | NA 232-668-6 220-239-6 | < 0.01% NA 0.02% |

| | | | | |
|-----------------------------|----------------------------------------------|-----------|-----------|-------|
| R6 Substrate | Ortho-Phenylenediamine Dihydrochloride (OPD) | 615-28-1 | 210-418-7 | 1.0% |
| R7 Hydrogen Peroxide | Hydrogen Peroxide | 7722-84-1 | 231-765-0 | 0.15% |

NA – Not Available

4. FIRST AID MEASURES

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| 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

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| 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

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| 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

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| 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 source material of a biological origin. As no known test method can provide complete assurance that biologicals will not transmit 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: 1 ppm for Hydrogen Peroxide per ACGIH

OELV/TWA: 1 ppm, 1.4 mg/m³ for Hydrogen Peroxide per OSHA

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 tPA IgG Coated Microwells | PET Buffer | tPA Standard 30 ng/mL | tPA Standard 0 ng/mL | Detection Antibody | Substrate | Hydrogen Peroxide |
|-----------------------|--------------------------------------|---------------|-----------------------|----------------------|--------------------|---------------|-------------------|
| Appearance | N/A | white powder | straw-colored powder | straw-colored powder | clear liquid | white powder | clear liquid |
| Odor | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| pH | N/A | 7.4 | N/A | 7.4 | 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 | water soluble | water soluble | water soluble | 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 | N/A | 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 |

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-Human tPA IgG Coated Microwells | Anti-Human tPA 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 |
| PET Buffer | Disodium Phosphate Sodium Chloride Trisodium EDTA Tween 20 | No Data Available 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 | No Data Available rabbit, >10,000 mg/kg No Data Available No Data Available |
| tPA Standard 30 ng/mL | Human tPA Normal Human Plasma | No Data Available No Data Available | No Data Available No Data Available | No Data Available No Data Available |
| tPA Standard 0 ng/mL | Normal Human Plasma | No Data Available | No Data Available | No Data Available |
| Detection Antibody | Anti-Human tPA IgG Peroxidase Type XII (from horseradish) Methylisothiazone | No Data Available No Data Available No Data Available | No Data Available No Data Available No Data Available | No Data Available No Data Available No Data Available |
| Substrate | Ortho-Phenylenediamine Dihydrochloride | No Data Available | No Data Available | No Data Available |
| Hydrogen Peroxide | Hydrogen Peroxide | No Data Available | No Data Available | 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).
 Causes skin damage/burns (due to Hydrogen Peroxide).
 Causes skin irritation (due to Ortho-Phenylenediamine Dihydrochloride).

Eye: Mild eye irritation in rabbit in 24 hours (due to Disodium Phosphate).
 Serious eye damage/burns (due to Hydrogen Peroxide).
 Causes eye irritation (due to Ortho-Phenylenediamine Dihydrochloride).

Inhalation: Toxic if inhaled, causes respiratory tract irritation (due to Ortho-Phenylenediamine Dihydrochloride). No Data Available.

11.3 Sensitization

Skin: May cause sensitization (due to Methylisothiazone).

Inhalation: 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.

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|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| 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 |
| Toxicity to Aquatic Life with long lasting effects (Ortho-Phenylenediamine Dihydrochloride) – No Data Available | |

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

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|-----------|---------------------------|-------------------------------------------------------------------------------|
| 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: | Proper Name For Shipping: | Phenylenediamines |
| | UN Number: | 1673 |
| | Hazard Class: | 6.1 |
| | Packing Group: | III |
| IMDG: | Proper Name For Shipping: | Phenylenediamines |
| | UN Number: | 1673 |
| | Hazard Class: | 6.1 |
| | Packing Group: | III |
| | 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:



Indication of Danger:

Warning, Danger, Toxic

Risk Code:

R20/21/22, R36/37/38, R43, R45

Safety Code:

S24/25, S26, S36/37/39, S46

Hazard Code:

H301, H302, H314, H315, H319, H332, H335, H341, H351, H410, H411

OSHA Hazards:

Toxic by ingestion, Oxidizer, Corrosive (Hydrogen Peroxide)

SARA 302 Components:

The following component(s) are subject to reporting levels established by SARA Title III, Section 302.

Hydrogen Peroxide

SARA 313 Components:

The following component(s) are subject to reporting levels established by SARA Title III, Section 313.

Ortho-Phenylenediamine Dihydrochloride

SARA 311/312 Hazards:

Acute Health Hazard (due to Hydrogen Peroxide, Ortho-Phenylenediamine Dihydrochloride).
 Chronic Health Hazard (due to Silica Gel, Hydrogen Peroxide, Ortho-Phenylenediamine Dihydrochloride).

California Prop 65 Components:

Warning. This product contains a chemical known to the State of California to cause cancer, birth defects or any other reproductive harm.

Ortho-Phenylenediamine Dihydrochloride

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.