Sekisui Diagnostics, LLC
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MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: SPECTROLYSE® PAI-1

1.2 Product REF: 101201

1.3 Configuration: Set of 7 reagent vials

1.4 Use of Product: For In Vitro Diagnostic Use.

1.5 Company

Manufacturer:
Sekisui Diagnostics, LLC
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2. HAZARDS IDENTIFICATION

2.1 Classification: Danger (due to the presence of para-nitroaniline in Plasminogen Activator Reagent)

2.2 Potential Health and Environmental Effects

Skin Exposure: Toxic if absorbed through skin.

Eye Exposure: May be harmful.

Inhalation Exposure: Toxic if inhaled.

Ingestion: Toxic if swallowed.

Environmental Exposure: Para-nitroaniline (Plasminogen Activator Reagent) is toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Reagent/Component	Chemical Name	CAS Number	EINECS No.	Concentration, w/v, %
1-chain Human tPA	Tissue-type Plasminogen Activator Ammonium Bicarbonate Bovine Serum Albumin	105857-23-6 1066-33-7 9048-46-8	NA 213-911-5 232-936-2	< 0.1% 7.91% 1.0%
tPA/PAI-1 Depleted Plasma	Human Plasma	NA	NA	100%
Plasminogen Activator Reagent	Human Glu-Plasminogen Imidazole Trisodium EDTA Tween 80 Poly-D-lysine Para-nitroaniline Sodium Azide	9001-91-6 288-32-4 85715-60-2 9005-65-6 27964-99-4 100-01-6 26628-22-8	232-641-9 206-019-2 205-758-8 NA NA 202-810-1 247-852-1	< 0.1% 0.21% 0.09% 0.05% < 0.1% 0.125% 0.01%
Acetate Buffer	Acetic Acid	64-19-7	200-580-7	6.0%

Imidazole Buffer (10X)	Imidazole Trisodium EDTA Tween 80	288-32-4 85715-60-2 9005-65-6	206-019-2 205-758-8 NA	3.4% 1.46% 0.8%
Stop Reagent	Potassium Acetate Guanidine Hydrochloride Acetic Acid	127-08-2 50-01-1 64-19-7	204-822-2 200-002-3 200-580-7	5.88% 30.5% 16.8%

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: The product contains human source material that and 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.

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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.

Plasminogen Activator Reagent (containing para-nitroaniline) is toxic if swallowed, targeting the liver, lung, heart and/or blood. It is toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

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 for the lyophilized product.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure Limit Values

TLV/TWA: 3.0 mg/m^3 for para-nitroaniline per ACGIH
TLV/TWA: 10 ppm for Aetic Acid per ACGIH
TLV/TWA: 0.1 mg/m^3 for Sodium Azide

OELV/TWA: 6 mg/m^3, 1 ppm for para-nitroaniline per OSHA
OELV/TWA: 25 mg/m^3, 10 ppm for Acetic Acid per OSHA
OELV/TWA: 25 mg/m^3, 10 ppm for Acetic Acid per NIOSH

TWA (Skin): 3 mg/m^3 for para-nitroaniline per NIOSH

TLV/STEL: 15 ppm for Acetic Acid per ACGIH
TLV/STEL: 0.3 mg/m^3 for Sodium Azide

TLV/Ceiling: 0.29 mg/m^3 for Sodium Azide, 0.11 ppm for Hydrazoic acid vapor per ACGIH

EU IOELV: 0.1 mg/m^3 (TWA) for Sodium Azide, 0.3 mg/m^3 (STEL) for Sodium Azide

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Property	1-Chain Human tPA	tPA/PAI-1 Depleted Plasma	Plasminogen Activator Reagent	Acetate Buffer	Imidazole Buffer (10X)	Stop Solution
Appearance	white powder	straw colored powder	white powder	clear, colorless liquid	clear, colorless liquid	clear, colorless liquid
Odor	NA	none	none	slight pungent	none	slight pungent
pH	NA	NA	NA	3.9	7.4	3.7
Freezing Point	NA	NA	NA	NA	NA	NA
Vapor Pressure	NA	NA	NA	NA	NA	NA
Specific Gravity	NA	NA	NA	NA	NA	NA
Solubility	water soluble	water soluble	water soluble	water soluble	water soluble	water soluble
Evaporation Rate	NA	NA	NA	NA	NA	NA
Viscosity	NA	NA	NA	NA	NA	NA
Surface Tension	NA	NA	NA	NA	NA	NA
Boiling Point	NA	NA	NA	NA	NA	NA
Melting Point	NA	NA	NA	NA	NA	NA
Flash Point	NA	NA	NA	NA	NA	NA
Lower Explosive Limit	NA	NA	NA	NA	NA	NA
Upper Explosive Limit	NA	NA	NA	NA	NA	NA
Flammability	NA	NA	NA	NA	NA	NA
Autoignition Temp.	NA	NA	NA	NA	NA	NA

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, nitrogen oxides, sodium oxides, and hydrogen chloride gas (Acetic Acid).

Warning: Sodium Azide may form explosive compounds, copper azide or lead azide, when in contact with laboratory plumbing.

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11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD_{50}	Inhalation LC_{50}	Dermal LD_{50}
1-Chain Human tPA	Tissue-type Plasminogen Activator Ammonium Bicarbonate Bovine Serum Albumin	No Data Available rat, 1,576 mg/kg No Data Available	No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available
tPA/PAI-1 Depleted Plasma	Human Plasma	No Data Available	No Data Available	No Data Available
Plasminogen Activator Reagent	Human Glu-Plasminogen Imidazole Trisodium EDTA Tween 80 Poly-D-lysine Para-nitroaniline Sodium Azide	No Data Available rat, 970 mg/kg No Data Available mouse, 25,000 mg/kg No Data Available rat, 750 mg/kg No Data Available	No Data Available No Data Available No Data Available No Data Available No Data Available No Data Available rat, 37 mg/m^3	No Data Available No Data Available No Data Available No Data Available No Data Available guinea pig, >500 mg/kg rabbit, 20 mg/kg
Acetate Buffer	Acetic Acid	rat, 3,310 mg/kg	mouse, 1 hr, 5,620 ppm	rabbit, 1,112 mg/kg
Imidazole Buffer	Imidazole Trisodium EDTA Tween 80	rat, 970 mg/kg No Data Available mouse, 25,000 mg/kg	No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available
Stop Solution	Potassium Acetate Guanidine Hydrochloride Acetic Acid	No Data Available No Data Available rat, 3,310 mg/kg	No Data Available No Data Available mouse, 1 hr, 5,620 ppm	No Data Available No Data Available rabbit, 1,112 mg/kg

11.2 Irritation

Skin: Corrosive to skin in rabbit (Imidazole).

Eye: Corrosive to the eye in rabbit (Acetic Acid).
Causes serious eye damage in rabbit (Imidazole).
Causes serious eye irritation (Guanidine Hydrochloride).

Inhalation: Causes skin irritation (Guanadine Hydrochloride).

11.3 Sensitization

Skin: May cause skin sensitization.

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

Imidazole is a presumed human reproductive toxicant. It may damage the unborn child.

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. Harmful to aquatic life. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Toxicity to fish (Acetic Acid)	LC50, pimephales promelas (fathead minnow) – 79-88 mg/L, 96 hours
Toxicity to fish (Acetic Acid)	LC50, Lepomis macrochirus – 75 mg/L, 96 hours
Toxicity to fish (Ammonium Bicarbonate)	LC50, Oncorhynchus (rainbow trout) – 16.8 -19.6 mg/L, 96 hours
Toxicity to fish (Imidazole)	LC50, Leuciscus idus (golden orfe) – 280 mg/L, 48 hours
Toxicity to fish (para-nitroaniline)	LC50, pimephales promelas (fathead minnow) – 85.7-142 mg/L, 96 hours
Toxicity to fish (para-nitroaniline)	LC50, Leuciscus idus (golden orfe) – 35 mg/L, 48 hours
Toxicity to fish (para-nitroaniline)	LC50, danio rerio (zebra fish) – 87.6 mg/L, 96 hours
Toxicity to daphnia (Acetic Acid)	EC50, daphnia magna (water flea) – 65 mg/L, 48 hours
Toxicity to daphnia (Imidazole)	EC50, daphnia magna (water flea) – 341.5 mg/L, 48 hours
Toxicity to daphnia (para-nitroaniline)	EC50, daphnia magna (water flea) – 17 mg/L, 48 hours
Toxicity to algae (Imidazole)	EC50, Scenedesmus quadricauda (green algae) – 133 mg/L, 72 hours
Toxicity to algae (para-nitroaniline)	EC50, NA – 68 mg/L, 24 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability Acetic Acid, aerobic, 99% biodegradable
Imidazole, aerobic, 86% biodegradable

12.4 Bioaccumulative potential: No Data Available

12.5 PBT assessment: No Data Available

12.6 Other adverse effects: Acetic Acid – Biochemical Oxygen Demand – 880 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:	Corrosive solid, basic, organic, n.o.s. (Imidazole)
	UN Number:	3263
	Hazard Class:	8
	Reportable Quantity:	Not Available
	Packing Group:	II
	Marine Pollutant:	No
	Poison Inhalation Hazard:	No
IATA:	Proper Name For Shipping:	Corrosive solid, basic, organic, n.o.s. (Imidazole)
	UN Number:	3263
	Hazard Class:	8
	Packing Group:	II

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IMDG:	Proper Name For Shipping:	Corrosive solid, basic, organic, n.o.s. (Imidazole)
	UN Number:	3263
	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:	Toxic.
Risk Code:	R21/22, R23/24/25, R26/27/28, R32, R50/53
Safety Code:	S24/25, S26, S36/37/39, S46, S29/56
Hazard Code:	H226, H301, H302, H311, H313, H314, H315, H318, H319, H331, H360, H373, H400, H402, H410

OSHA Hazards:	Toxic by inhalation, toxic by ingestion, toxic by skin absorption (para-nitroaniline). Target organs are primarily the central nervous system and the brain. Combustible liquid, corrosive, skin sensitizer (Acetic Acid). Corrosive, teratogen, harmful by ingestion (Imidazole).
SARA 302 Components:	No chemicals in this product are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components:	The following components are subject to reporting levels established by SARA Title III, Section 313. Para-nitroaniline
SARA 311/312 Hazards:	Fire Hazard, Acute Health Hazard, Chronic Health Hazard
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.