Sekisui Diagnostics, LLC
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Tel. (203) 602-7777 Fax (203) 602-2221

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: ACTICHROME® TFPI

1.2 Product REF: 848

1.3 Configuration: Set of 9 Reagents

1.4 Use of Product: For Research Use Only.

1.5 Company

Manufacturer:
Sekisui Diagnostics, LLC
500 West Avenue
Stamford, CT 06902 USA
Tel: (203) 602 7777
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Pfungstadt 64319 Germany
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2. HAZARDS IDENTIFICATION

2.1 Classification: Danger (due to para-nitroaniline in SPECTROZYME FXa), Toxic, Biohazard, Irritant

2.2 Potential Health and Environmental Effects

Skin Exposure: Toxic if absorbed through skin (due to SPECTROZYME FXa).

Eye Exposure: May be harmful.

Inhalation Exposure: Toxic if inhaled (due to SPECTROZYME FXa).

Ingestion: Toxic if swallowed (due to SPECTROZYME FXa).

Environmental Exposure: Para-nitroaniline (SPECTROZYME FXa) 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/EC No.	Concentration, w/v, %
Assay Buffer, 5X	Tris-Hydrochloride Sodium Chloride Bovine Serum Albumin D-Trehalose Dihydrate	1185-53-1 7647-14-5 9048-46-8 6138-23-4	241-684-5 231-598-3 232-936-2 202-739-6	3.94% 2.92% 0.5% 4.84%
SPECTROZYME® FXa	Para-nitroaniline (4-nitroaniline)	100-01-6	202-810-1	0.15%
TFPI Depleted Plasma	Human Plasma	NA	NA	100%
TFPI Reference Plasma	Human Plasma	NA	NA	100%
Human Factor X	Human Factor X Tris-Hydrochloride Sodium Chloride Bovine Serum Albumin D-Trehalose Dihydrate	9002-05-05 1185-53-1 7647-14-5 9048-46-8 6138-23-4	3.4.21.6 241-684-5 231-598-3 232-936-2 202-739-6	< 0.1% 0.79% 0.58% 0.1% 0.97%

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Relipidated Tissue Factor	Relipidated Human Tissue Factor Tris Sodium Chloride	NA 77-86-1 7647-14-5	NA 201-064-4 231-598-3	< 0.001% 0.61% 0.58%
Human Factor VIIa Reagent	Human Factor VIIa Tris-Hydrochloride Sodium Chloride Calcium Chloride Bovine Serum Albumin D-Trehalose Dihydrate Hexadimethrine Bromide	9001-25-6 1185-53-1 7647-14-5 10043-52-4 9048-46-8 6138-23-4 28728-55-4	3.4.21.21 241-684-5 231-598-3 233-140-8 232-936-2 202-739-6 NA	< 0.1% 0.79% 0.58% 0.4% 0.1% 0.97% < 0.1%
TFPI Standard	Human Plasma	NA	NA	100%

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.

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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: 3.0 mg/m^3 for para-nitroaniline per ACGIH
OELV/TWA: 6 mg/m^3, 1 ppm for para-nitroaniline per OSHA
TWA (Skin): 3 mg/m^3 for para-nitroaniline 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Assay Buffer	SPECTROZYME FXa	TFPI Depleted Plasma	TFPI Reference Plasma	Human Factor X	Relipidated Tissue Factor	Human Factor VIIa	TFPI Standard
Appearance	N/A	white powder	straw-colored powder	straw-colored powder	white powder	white powder	white powder	straw-colored powder
Odor	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
pH	7.6							
Freezing Point	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
Specific Gravity	N/A	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	water soluble
Evaporation Rate	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
Surface Tension	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
Melting Point	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
Lower Explosive Limit	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
Flammability	N/A	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

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}
Assay Buffer	Tris-Hydrochloride Sodium Chloride Bovine Serum Albumin D-Trehalose Dihydrate	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 No Data Available
SPECTROZYME FXa	Para-nitroaniline	rat, 750 mg/kg	No Data Available	guinea pig, >500 mg/kg
TFPI Depleted Plasma	Normal Human Plasma	No Data Available	No Data Available	No Data Available
TFPI Reference Plasma	Normal Human Plasma	No Data Available	No Data Available	No Data Available
Human Factor X	Human Factor X Tris-Hydrochloride Sodium Chloride Bovine Serum Albumin D-Trehalose Dihydrate	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
Relipidated Tissue Factor	Relipidated Human Tissue Factor Tris Sodium Chloride	No Data Available rat, 5,900 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 rabbit, >10,000 mg/kg
Human Factor VIIa	Human Factor VIIa Tris-Hydrochloride Sodium Chloride Calcium Chloride Bovine Serum Albumin D-Trehalose Dihydrate Hexadimethrine Bromide	No Data Available No Data Available No Data Available rat, 1,000 mg/kg No Data Available No Data Available rat, >1,000 mg/kg	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 No Data Available rabbit, >10,000 mg/kg No Data Available No Data Available No Data Available No Data Available
TFPI Standard	Normal Human Plasma	No Data Available	No Data Available	No Data Available

11.2 Irritation

Skin: No Data Available.

Eye: Severe eye irritation in rat (due to Calcium Chloride)

Inhalation: No Data Available.

11.3 Sensitization

Skin: No Data Available.

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. Para-nitroaniline is toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

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 fish (Calcium Chloride)	LC50, Lepomis macrochirus – 10,650 mg/L, 96 hours
Toxicity to daphnia (para-nitroaniline)	EC50, daphnia magna (water flea) – 17 mg/L, 48 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 daphnia (Calcium Chloride)	EC50, Daphnia magna (water flea) – 52 mg/L, 48 hours
Toxicity to daphnia (Tris-Hydrochloride)	EC50, Daphnia – >100 mg/L, 48 hours
Toxicity to algae (para-nitroaniline)	EC50, NA – 68 mg/L, 24 hours
Toxicity to algae (Tris-Hydrochloride)	EC50, other microorganisms – >1,000 mg/L, 3 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability: No Data Available

12.4 Bioaccumulative potential: Danio rerio (zebra fish) – 96 hours (due to para-nitroaniline - SPECTROZYME FXa)
Bioconcentration factor (BCF): 4.4 (due to para-nitroaniline - SPECTROZYME FXa)

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:	Nitroanilines
	UN Number:	1661
	Hazard Class:	6.1
	Reportable Quantity:	5000 lbs.
	Packing Group:	II
	Marine Pollutant:	No
	Poison Inhalation Hazard:	No
IATA:	Proper Name For Shipping:	Nitroanilines
	UN Number:	1661
	Hazard Class:	6.1
	Packing Group:	II

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IMDG:	Proper Name For Shipping:	Nitroanilines
	UN Number:	1661
	Hazard Class:	6.1
	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:	H301, H302, H303, H311, H313, H315, H319, H331, H334, H335, H373, H400, H410, H411

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.
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:	Acute Health Hazard (due to Para-nitroaniline)
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.