Sekisui Diagnostics, LLC
500 West Avenue, Stamford, CT 06902
Tel. (203) 602-7777 Fax (203) 602-2221

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: ACTICHROME® AT III

1.2 Product REF: 838

1.3 Configuration: Set of 18 reagent vials

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:
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Kaplangeisse 35
Pfungstadt 64319 Germany
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2. HAZARDS IDENTIFICATION

2.1 Classification: Danger (due to the presence of para-nitroaniline in SPECTROZYME TH)

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 (SPECTROZYME TH) 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, %
Bovine Thrombin	Bovine Thrombin	9002-04-4	232-6948-7	< 0.01%
	Tris	77-86-1	201-064-4	0.12%
	Sodium Chloride	7647-14-5	231-598-3	0.23%
	Bovine Serum Albumin	9048-46-8	232-936-2	0.4%
	D-Mannitol	69-65-8	200-711-8	0.38%
Assay Buffer (10X)	Tris-Hydrochloride	1185-53-1	241-684-5	7.88%
	Sodium Chloride	7647-14-5	231-598-3	10.22%
	Trisodium EDTA	85715-60-2	205-758-8	2.85%
	Sodium Heparin	9041-08-1	NA	10 USP/mL
SPECTROZYME® TH	Para-nitroaniline (4-nitroaniline)	100-01-6	202-810-1	0.15%

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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 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. SPECTROZYME TH (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.

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Bovine Thrombin	Assay Buffer	SPECTROZYME TH
Appearance	white powder	clear, colorless liquid	white powder
Odor	NA	None	NA
pH	NA	8.4	NA
Freezing Point	NA	NA	NA
Vapor Pressure	NA	NA	NA
Specific Gravity	NA	NA	NA
Solubility	water soluble	NA	water soluble
Evaporation Rate	NA	NA	NA
Viscosity	NA	NA	NA
Surface Tension	NA	NA	NA
Boiling Point	NA	NA	NA
Melting Point	NA	NA	NA
Flash Point	NA	NA	NA
Lower Explosive Limit	NA	NA	NA
Upper Explosive Limit	NA	NA	NA
Flammability	NA	NA	NA
Autoignition Temp.	NA	NA	NA

NA = not available

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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.

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

11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD_{50}	Inhalation LC_{50}	Dermal LD_{50}
Bovine Thrombin	Bovine Thrombin	NA	NA	mouse, > 3,000 mg/kg
	Tris	NA	NA	NA
	Sodium Chloride	NA	rat,1 hr >42,000 mg/m^3	rabbit, >10,000 mg/kg
	Bovine Serum Albumin	NA	NA	NA
	D-Mannitol	NA	NA	NA
Assay Buffer (10X)	Tris-Hydrochloride	NA	NA	NA
	Sodium Chloride	NA	rat,1 hr >42,000 mg/m^3	rabbit, >10,000 mg/kg
	Trisodium EDTA	NA	NA	NA
	Sodium Heparin	mouse, > 5,000 mg/kg	NA	NA
SPECTROZYME TH	Para-nitroaniline	rat, 750 mg/kg	NA	guinea pig, >500 mg/kg

NA – Not Available

11.2 Irritation

Skin: No Data Available

Eye: No Data Available

Inhalation: No Data Available

11.3 Sensitization

Skin: Prolonged or repeated exposure may cause allergic reactions in certain individuals (Bovine Thrombin).

Inhalation: Prolonged or repeated exposure may cause allergic reactions in certain individuals (Bovine Thrombin).

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.

11.4 Mutagenicity

No data available

11.4 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 daphnia (para-nitroaniline)	EC50, daphnia magna (water flea) – 17 mg/L, 48 hours
Toxicity to algae (para-nitroaniline)	EC50, NA – 68 mg/L, 24 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
Bioconcentration factor (BCF): 4.4

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:	RR21/22, R23/24/25, R26/27/28, R32, R50/53
Safety Code:	S24/25, S26, S36/37/39, S46, S29/56
Hazard Code:	H301, H302, H311, H313, H315, H319, H331, H373, H400, 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.
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
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.