

## 1. Identification

<b>Product identifier</b>	<b>Human Factor VIIa, in 848 ACTICHROME® TFPI</b>
<b>Other means of identification</b>	
<b>Product code</b>	Human Factor VIIa reagent 848 ACTICHROME® TFPI
<b>Recommended use</b>	The ACTICHROME® TFPI is a chromogenic assay intended for the measurement of Tissue Factor Pathway Inhibitor activity in human plasma. Research use only.
<b>Recommended restrictions</b>	Use in accordance with supplier's recommendations.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Corporate Headquarters</b>	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042 questions@sekisuidiagnostics.com
<b>Contact person</b>	Americas 1-760-476-3962
<b>Emergency Telephone Numbers</b>	Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
<b>OSHA defined hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.
<b>Precautionary statement</b>	
<b>Prevention</b>	Avoid breathing dust. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves. Wear eye/face protection.
<b>Response</b>	If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	CAS number	%
2-Amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride	1185-53-1	25 - 30

Sodium chloride	7647-14-5	15 - 25
Calcium chloride, dihydrate	10035-04-8	10 - 20
Hexadimethrine bromide	28728-55-4	5 - 10

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

#### 4. First-aid measures

**Inhalation** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

**Skin contact** Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

**Eye contact** Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed** May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically.

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. If you feel unwell, seek medical advice (show the label where possible).

#### 5. Fire-fighting measures

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted. Will burn if involved in a fire.

#### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up** Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

**Precautions for safe handling** Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities** Store locked up. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	No exposure standards allocated.
<b>Appropriate engineering controls</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Eye wash facilities and emergency shower must be available when handling this product.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety goggles and a face shield.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.
<b>Other</b>	Wear appropriate chemical resistant clothing.
<b>Respiratory protection</b>	In case of inadequate ventilation or risk of inhalation of dust or fumes, use suitable respiratory equipment.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Lyophilized powder.
<b>Color</b>	White.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble in water.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Keep away from heat.
<b>Incompatible materials</b>	Strong acids. Strong oxidizing agents. Reducing agents.
<b>Hazardous decomposition products</b>	Carbon oxides. Nitrogen oxides.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Dust may irritate respiratory system.
<b>Skin contact</b>	Causes skin irritation.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	May cause discomfort if swallowed.

**Symptoms related to the physical, chemical and toxicological characteristics** Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. May cause redness and pain.

### Information on toxicological effects

**Acute toxicity** May cause discomfort if swallowed.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
Calcium chloride, dihydrate (CAS 10035-04-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 1000 mg/kg
Hexadimethrine bromide (CAS 28728-55-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 1000 mg/kg

**Skin corrosion/irritation** Causes skin irritation.

**Serious eye damage/eye irritation** Causes serious eye irritation.

### Respiratory or skin sensitization

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** Not a skin sensitizer.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** Not classifiable as to carcinogenicity to humans.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

**Specific target organ toxicity - single exposure** May cause respiratory irritation.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not classified.

**Further information** No other specific acute or chronic health impact noted.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
Sodium chloride (CAS 7647-14-5)		
<b>Aquatic</b>		
Crustacea	EC50 Water flea (Daphnia magna)	874 mg/l, 48 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>		
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

### 15. Regulatory information

<b>US federal regulations</b>	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	Yes
<b>SARA 313 (TRI reporting)</b>	Not regulated.
<b>Other federal regulations</b>	
<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 08-April-2015**Revision date** -**Version #** 01**NFPA ratings****References**ACGIH  
IARC Monographs. Overall Evaluation of Carcinogenicity  
HSDB® - Hazardous Substances Data Bank

**Disclaimer**

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.