

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

<b>Trade name or designation of the mixture</b>	Relipidated Tissue Factor in 848 ACTICHROME® TFPI
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	Relipidated Tissue Factor in 848 ACTICHROME® TFPI
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	20-July-2017
<b>Supersedes date</b>	08-April-2015

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

<b>Identified uses</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>Uses advised against</b>	Use in accordance with supplier's recommendations.

### 1.3. Details of the supplier of the safety data sheet

**Corporate Headquarters** BioMedica Diagnostics Inc.  
 94 Wentworth Road, PO Box 1030  
 Windsor, Nova Scotia CANADA B0N 2T0

**Contact person** Corporate Phone: 1-902-798-5105  
 Corporate Fax: 1-902-798-1025  
 Email: info@biomedicadiagnostics.com  
 Website: www.biomedicadiagnostics.com

**1.4. Emergency telephone number** US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924  
 International +1-813-248-0585  
 Australia 1-300-954-583  
 Brazil 0-800-591-6042  
 China 400-120-0751  
 India 000-800-100-4086  
 Mexico 01-800-099-0731

**Contract number** MIS9591327

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

**Classification** Xi;R36/37/38

The full text for all R-phrases is displayed in section 16.

#### Classification according to Regulation (EC) No 1272/2008 as amended

##### Health hazards

Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.
Specific target organ toxicity - single exposure	Category 3 respiratory tract irritation	H335 - May cause respiratory irritation.

##### Hazard summary

<b>Physical hazards</b>	Not classified for physical hazards.
<b>Health hazards</b>	Irritating to eyes, respiratory system and skin.
<b>Environmental hazards</b>	Not classified for hazards to the environment.
<b>Specific hazards</b>	Avoid contact with eyes and skin. Do not ingest or inhale.
<b>Main symptoms</b>	May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

### 2.2. Label elements

**Label according to Regulation (EC) No. 1272/2008 as amended****Hazard pictograms****Signal word**

Warning

**Hazard statements**

H315 Causes skin irritation.  
 H319 Causes serious eye irritation.  
 H335 May cause respiratory irritation.

**Precautionary statements****Prevention**

P261 Avoid breathing dust.  
 P264 Wash thoroughly after handling.  
 P271 Use only outdoors or in a well-ventilated area.  
 P280 Wear protective gloves.  
 P280 Wear eye/face protection.

**Response**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
 P332 + P313 If skin irritation occurs: Get medical advice/attention.  
 P362 + P364 Take off contaminated clothing and wash it before reuse.  
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P337 + P313 If eye irritation persists: Get medical advice/attention.  
 P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
 P312 Call a POISON CENTER/doctor if you feel unwell.

**Storage**

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.  
 P405 Store locked up.

**Disposal**

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Supplemental label information** None.

**2.3. Other hazards** Not a PBT or vPvB substance or mixture.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****General information**

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium chloride	15 - 25	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
<b>Classification:</b>					<b>DSD:</b> - <b>CLP:</b> -
Tris-(hydroxymethyl)aminomethane	10 - 20	77-86-1 201-064-4	-	-	
<b>Classification:</b>					<b>DSD:</b> Xi;R36/37/38 <b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335
2-Amino-2-(hydroxymethyl)propane-1, 3-diol hydrochloride	5 - 10	1185-53-1 214-684-5	-	-	
<b>Classification:</b>					<b>DSD:</b> Xi;R36-37-38 <b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335

**List of abbreviations and symbols that may be used above**

DSD: Directive 67/548/EEC.  
 CLP: Regulation No. 1272/2008.

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4: First aid measures

<b>General information</b>	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).
<b>4.1. Description of first aid measures</b>	
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or doctor/physician if you feel unwell.
<b>Skin contact</b>	Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
<b>Eye contact</b>	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.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.
<b>4.3. Indication of any immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.

## SECTION 5: Firefighting measures

<b>General fire hazards</b>	No unusual fire or explosion hazards noted. Will burn if involved in a fire.
<b>5.1. Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>5.2. Special hazards arising from the substance or mixture</b>	During fire, gases hazardous to health may be formed.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in section 8 of the SDS.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	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.
<b>6.4. Reference to other sections</b>	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Minimise dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	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).
<b>7.3. Specific end use(s)</b>	The ACTICHROME® TFPI is a chromogenic assay intended for the measurement of Tissue Factor Pathway Inhibitor activity in human plasma. Research use only.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

<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>Recommended monitoring procedures</b>	Follow standard monitoring procedures.
<b>Derived no-effect level (DNEL)</b>	Not available.
<b>Predicted no effect concentrations (PNECs)</b>	Not available.

### 8.2. Exposure controls

<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 engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn. 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.
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### Individual protection measures, such as personal protective equipment

<b>General information</b>	Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
<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>Hygiene measures</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.
<b>Environmental exposure controls</b>	Environmental manager must be informed of all major releases.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Lyophilized powder.
<b>Colour</b>	White.
<b>Odour</b>	Not available.
<b>Odour 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>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.

Relative density	Not available.
Solubility(ies)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

## SECTION 10: Stability and reactivity

10.1. Reactivity	The product is non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong acids. Strong oxidising agents. Reducing Agents.
10.6. Hazardous decomposition products	Carbon oxides. Nitrogen oxides.

## SECTION 11: Toxicological information

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

### Information on likely routes of exposure

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

**Symptoms** Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. May cause redness and pain.

### 11.1. Information on toxicological effects

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

Components	Species	Test results
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Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)

#### Acute

Oral

LD50

Rat

5900 mg/kg

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

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

**Respiratory sensitisation** Not a respiratory sensitiser.

**Skin sensitisation** Not a skin sensitiser.

**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.

**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.

**Mixture versus substance information** Not available.

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

## SECTION 12: Ecological information

**12.1. Toxicity** 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 ( <i>Daphnia magna</i> )	874 mg/l, 48 hours

**12.2. Persistence and degradability** No data is available on the degradability of this product.

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water (log Kow)

Tris-(hydroxymethyl)aminomethane (CAS 77-86-1) -2.31 (20°C)

**Bioconcentration factor (BCF)** Not available.

**12.4. Mobility in soil** No data available.

**12.5. Results of PBT and vPvB assessment** Not a PBT or vPvB substance or mixture.

**12.6. Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Residual waste** 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).

**Contaminated packaging** 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.

**EU waste code** The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Disposal methods/information** 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.

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

### RID

Not regulated as dangerous goods.

### ADN

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**  
Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**  
Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**  
Not listed.

**Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended**  
Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA**  
Not listed.

#### **Authorisations**

**Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**  
Not listed.

#### **Restrictions on use**

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**  
Not listed.

**Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended**  
Not listed.

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended**  
Not listed.

#### **Other EU regulations**

**Directive 2012/18/EU on major accident hazards involving dangerous substances**  
Not listed.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**  
Not listed.

**Directive 94/33/EC on the protection of young people at work**  
Not listed.

#### **Other regulations**

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

#### **National regulations**

Follow national regulation for work with chemical agents.

#### **15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out.

## **SECTION 16: Other information**

#### **List of abbreviations**

DNEL: Derived No-Effect Level.  
PNEC: Predicted No-Effect Concentration.

#### **References**

Not available.

#### **Information on evaluation method leading to the classification of mixture**

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

#### **Full text of any statements or R-phrases and H-statements under Sections 2 to 15**

R36 Irritating to eyes.  
R36/37/38 Irritating to eyes, respiratory system and skin.  
R37 Irritating to respiratory system.  
R38 Irritating to skin.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

#### **Training information**

Follow training instructions when handling this material.

**Disclaimer**

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