

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

1.1. Product identifier

Trade name or designation of the mixture	Human Factor X, in 848 ACTICHROME® TFPI
Registration number	-
Synonyms	None.
Product code	848 ACTICHROME® TFPI
Issue date	01-December-2017
Version number	02
Revision date	20-July-2017
Supersedes date	08-April-2015

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

Identified uses	The ACTICHROME® TFPI is a chromogenic assay intended for the measurement of Tissue Factor Pathway Inhibitor activity in human plasma. Research use only.
Uses advised against	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

Physical hazards	Not classified for physical hazards.
Health hazards	Irritating to eyes, respiratory system and skin.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms	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
2-Amino-2-(hydroxymethyl)propane-1, 3-diol hydrochloride	30 - 40	1185-53-1 214-684-5	-	-	
Classification:		DSD: Xi;R36-37-38			CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335
Sodium chloride	20 - 30	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification:		DSD: -			CLP: -

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**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).

4.1. Description of first aid measures

Inhalation	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.
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.

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

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

SECTION 5: Firefighting measures

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

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

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

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

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

Special fire fighting procedures Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in section 8 of the SDS.

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

6.3. Methods and material 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.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling 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.

7.2. 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).

7.3. Specific end use(s) 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

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	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

General information	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.
Eye/face protection	Wear safety goggles and a face shield.
Skin protection	
- Hand protection	Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.
- Other	Wear appropriate chemical resistant clothing.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust or fumes, use suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.
Environmental exposure controls	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

Physical state	Solid.
Form	Lyophilized powder.
Colour	White.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapour pressure Not available.

Vapour density 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.
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.
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Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
Aquatic		
Crustacea	EC50 Water flea (Daphnia magna)	874 mg/l, 48 hours

12.2. Persistence and degradability	No data is available on the degradability of this product.
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12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow) Not available.

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.

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