

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

1.1. Product identifier

Trade name or designation of the mixture	FRET Substrate
Registration number	-
Synonyms	None.
Product code	in 812 & 812RUO, ACTIFLUOR™ ADAMTS13 Activity
Issue date	01-December-2017
Version number	02
Revision date	14-July-2017
Supersedes date	21-June-2015

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

Identified uses	The ACTIFLUOR™ ADAMTS13 Activity assay is a fluorescence resonance energy transfer (FRET) assay for the measurement of ADAMTS13 in human plasma.
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
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Contract number	MIS9591327
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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 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.

Hazard summary	Irritating to eyes and skin.
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2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms



Signal word	Warning
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Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statements

Prevention

P264 Wash thoroughly after handling.
P280 Wear eye protection/face protection.
P280 Wear protective gloves.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P362 Take off contaminated clothing and wash before reuse.

Storage

None.

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	80 - 90	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification:	-				
4-Morpholinopropansulphonic acid	10 - <20	1132-61-2 214-478-5	-	-	
Classification:	Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				

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

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 Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

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

Avoid prolonged exposure. Avoid contact with skin and eyes.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well-ventilated place. Store in a closed container away from incompatible materials.

7.3. Specific end use(s)

The ACTIFLUOR™ ADAMTS13 Activity assay is a fluorescence resonance energy transfer (FRET) assay for the measurement of ADAMTS13 in human plasma.

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.

Exposure guidelines

No exposure standards allocated.

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.

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	White powder.
Physical state	Solid.
Form	Powder.
Colour	Not available.
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)	Water soluble.
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	Stable at normal conditions.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidising agents. Strong acids.
10.6. Hazardous decomposition products	Hydrogen chloride gas. Sodium 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 eye irritation.

Ingestion	May cause discomfort if swallowed.
Symptoms	Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

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 classified.
Skin sensitisation	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity	No toxicity data noted for the ingredient(s).
12.2. Persistence and degradability	No data available.
12.3. Bioaccumulative potential	No data available.
Partition coefficient n-octanol/water (log Kow)	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
12.5. Results of PBT and vPvB assessment	Not a PBT or vPvB substance or mixture.
12.6. Other adverse effects	No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
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. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

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 EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

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

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

References

ACGIH
HSDB® - Hazardous Substances Data Bank
IARC Monographs. Overall Evaluation of Carcinogenicity

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 H-statements
not written out in full under
Sections 2 to 15**

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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