BIOMEDICA

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation

Assay Buffer

of the mixture

Registration number

Synonyms None.

Product code Assay buffer, 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 Assorted.

Uses advised againstUse 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 Regulation (EC) No 1272/2008 as amended

Health hazards

exposure

Acute toxicity, oral Category 4 H302 - Harmful if swallowed.

Acute toxicity, dermal Category 3 H311 - Toxic in contact with skin.

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 Category 3 respiratory tract irritation

H335 - May cause respiratory irritation.

Environmental hazards

Hazardous to the aquatic environment, Category 2 H411 - Toxic to aquatic life with

long-term aquatic hazard long lasting effects.

Hazard summary

Toxic in contact with skin. Harmful if swallowed. Irritating to eyes, respiratory system and skin.

2.2. Label elements

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

Contains: 4-Morpholinopropansulphonic acid, Sodium azide

Assay Buffer SDS UK

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Hazard pictograms



Signal word Danger

Hazard statements

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention

P261 Avoid breathing dust.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.
P280 Wear eye protection/face protection.
P280 Wear protective gloves/protective clothing.

Response

P301 + P312 IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

P312 Call a POISON CENTRE or doctor/physician if you feel unwell.

P330 Rinse mouth.

P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P361 Remove/Take off immediately all contaminated clothing.
Take off contaminated clothing and wash before reuse.

P391 Collect spillage.

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 EUH032 - Contact with acids liberates very toxic gas.

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 |
|----------------------------------|--|-------------|-------------------------|------------------------|--------------|-------|
| 4-Morpholinopropansulphonic acid | | 60 - 70 | 1132-61-2 214-478-5 | - | - | |
| Classification: | Skin Irrit. 2 | H315, Eye I | rrit. 2;H319, STOT | SE 3;H335 | | |
| Sodium chloride | | 15 - 20 | 7647-14-5 231-598-3 | 01-2119485491-33-XXXX | - | |
| Classification: | - | | | | | |
| Calcium chloride, dihydrate | | 10 - 15 | 10035-04-8 | - | - | |
| Classification: | Eye Irrit. 2; | H319 | | | | |
| Sodium azide | | 1 - 4 | 26628-22-8 247-852-1 | - | 011-004-00-7 | # |
| Classification: | Acute Tox. 2;H300, Acute Tox. 1;H310, Aquatic Acute 1;H400, Aquatic Chronic 1;H410 | | | | | |

List of abbreviations and symbols that may be used above

#: This substance has been assigned Community workplace exposure limit(s).

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

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.

4.1. Description of first aid measures

Inhalation Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician if

symptoms develop or persist.

Skin contact Wash off immediately with plenty of water. Call a POISON CENTRE or doctor/physician if you feel

unwell. Get medical attention if irritation develops and persists.

Eve contact In case of contact, immediately flush eves with fresh water for at least 15 minutes while holding the

eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get Ingestion

immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms include itching, burning, redness and tearing.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards Will burn if involved in a fire.

5.1. Extinguishing media

Suitable extinguishing

media

surrounding fire. None known.

Unsuitable extinguishing media

5.2. Special hazards arising

from the substance or mixture

Fire will generate toxic and irritating gases. When heated to decomposition, may produce hydrazoic acid fumes.

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

5.3. Advice for firefighters

Special protective equipment for firefighters

Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. 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

Avoid dust formation. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

For emergency responders

Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental precautions

Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

6.3. Methods and material for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per

Section 13.

6.4. Reference to other sections

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe

handling

Avoid inhalation of dust. Avoid contact with skin and eyes. Provide appropriate exhaust ventilation at places where dust is formed. Wash thoroughly after handling. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

7.3. Specific end use(s)

Assorted.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

| Components | Туре | Value | |
|-------------------------------|------|-----------|--|
| Sodium azide (CAS 26628-22-8) | STEL | 0.3 mg/m3 | |
| , | TWA | 0.1 mg/m3 | |

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

| Components | Туре | Value | |
|-------------------------------|------|-----------|--|
| Sodium azide (CAS 26628-22-8) | STEL | 0.3 mg/m3 | |
| , | TWA | 0.1 mg/m3 | |

No biological exposure limits noted for the ingredient(s). **Biological limit values**

Recommended monitoring

procedures

Follow standard monitoring procedures.

Not available. Derived no-effect level (DNEL) Not available. Predicted no effect

concentrations (PNECs)

Exposure guidelines

UK EH40 WEL: Skin designation Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

8.2. Exposure controls

Appropriate engineering

Observe occupational exposure limits and minimise the risk of inhalation of dust and fumes.

controls

Individual protection measures, such as personal protective equipment

General information Personal protective equipment should be chosen according to the CEN standards and in

discussion with the supplier of the personal protective equipment.

Eye/face protection Wear approved safety glasses or goggles.

Skin protection

Wear appropriate chemical resistant gloves. - Hand protection Remove contaminated clothing promptly. - Other

Respiratory protection In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment

with particle filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure

controls

Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance White powder.

Physical state Solid. Powder. **Form** Colour \//hit₽ None Odour

Not available. **Odour threshold** Not available. pН 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)

Assay Buffer SDS UK

927119 Version #: 02 Revision date: 14-July-2017 Issue date: 01-December-2017 Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

Not available.

Not available. Vapour pressure Not available. Vapour density Not available. Relative density Solubility(ies) Soluble.

Partition coefficient

Not available.

(n-octanol/water)

Auto-ignition temperature Not available Not available. **Decomposition temperature** Not available. **Viscosity Explosive properties** Not available. **Oxidizing properties** Not available.

No relevant additional information available. 9.2. Other information

SECTION 10: Stability and reactivity

The product is stable and non reactive under normal conditions of use, storage and transport. 10.1. Reactivity

Material is stable under normal conditions. 10.2. Chemical stability 10.3. Possibility of hazardous Contact with acids liberates toxic gas.

reactions

Contact with acids. Heat, flames and sparks. 10.4. Conditions to avoid

Strong oxidising agents. Strong acids. Strong reducing agents. 10.5. Incompatible materials

Thermal decomposition can lead to release of irritating gases and vapors, including hydrazoic acid 10.6. Hazardous

decomposition products vapor. Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Inhalation Dust may irritate respiratory system. Skin contact Toxic in contact with skin. Irritating to skin.

Causes serious eye irritation. Eye contact

Harmful if swallowed. Ingestion

Symptoms Symptoms include itching, burning, redness and tearing.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed. Toxic in contact with skin.

Test results Components

Calcium chloride, dihydrate (CAS 10035-04-8)

Acute Oral

LD50 Rat > 1000 mg/kg

Sodium azide (CAS 26628-22-8)

Acute Dermal

Rabbit LD50

20 mg/kg

Oral

LD50 Rat 27 mg/kg

Skin corrosion/irritation Causes skin irritation.

Causes serious eye irritation. Serious eye damage/eye

irritation

Respiratory sensitisation Not classified. Not classified. Skin sensitisation Not classified. Germ cell mutagenicity

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Not classifiable as to carcinogenicity to humans. Carcinogenicity

Not classified. Reproductive toxicity

Specific target organ toxicity -

single exposure

May cause respiratory irritation.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Mixture versus substance

information

Not classified. Not available.

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

SECTION 12: Ecological information

12.1. Toxicity Toxic to aquatic life with long lasting effects.

Components **Species** Test results

Sodium azide (CAS 26628-22-8)

Aquatic

EC50 Pseudokirchnerella subcapitata 0.35 mg/l, 96 hours Algae LC50 Fish Fish 5.7 mg/l, 96 hours

12.2. Persistence and

degradability

No data is available on the degradability of this product.

12.3. Bioaccumulative potential Not available. Partition coefficient Not available.

n-octanol/water (log Kow)

Bioconcentration factor (BCF) Not available. No data available. 12.4. Mobility in soil

The product is soluble in water. Mobility in general

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.

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

disposal company.

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This Disposal methods/information

> preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain,

flush with a large volume of water to prevent azide build-up.

SECTION 14: Transport information

ADR

14.1. UN number

14.2. UN proper shipping Toxic solid, inorganic, n.o.s. (Sodium azide)

name

14.3. Transport hazard class(es)

Class 6.1 Subsidiary risk 6.1 Label(s) 60 Hazard No. (ADR) **Tunnel restriction code** Ε 14.4. Packing group Ш 14.5. Environmental hazards Yes

14.6. Special precautions

Read safety instructions, SDS and emergency procedures before handling.

for user

RID

14.1. UN number **UN3288**

SDS UK Assay Buffer

14.2. UN proper shipping Toxic solid, inorganic, n.o.s. (Sodium azide) name

14.3. Transport hazard class(es)
Class 6.1
Subsidiary risk -

Label(s) 6.1

14.4. Packing group III

14.5. Environmental hazards Yes

14.6. Special precautions Read safety instructions, SDS and emergency procedures before handling.

for user

ADN

14.1. UN number UN3288

14.2. UN proper shipping Toxic solid, inorganic, n.o.s. (Sodium azide)

name

14.3. Transport hazard class(es)

Class 6.1
Subsidiary risk Label(s) 6.1

14.4. Packing group III

14.5. Environmental hazards Yes

14.6. Special precautions Read safety instructions, SDS and emergency procedures before handling.

for user

IATA

14.1. UN number UN3288

14.2. UN proper shipping Toxic solid, inorganic, n.o.s. (Sodium azide)

name

14.3. Transport hazard class(es)

Class 6.1
Subsidiary risk Label(s) 6.1

14.4. Packing group III

14.5. Environmental hazards Yes
ERG Code 6L

14.6. Special precautions

for user

Read safety instructions, SDS and emergency procedures before handling.

IMDG

14.1. UN number UN3288

14.2. UN proper shipping TOXIC SOLID, INORGANIC, N.O.S. (Sodium azide)

name

14.3. Transport hazard class(es)

Class 6.1
Subsidiary risk Label(s) 6.1
14.4. Packing group III
14.5. Environmental hazards
Marine pollutant Yes

EmS F-A, S-A

14.6. Special precautions

for user

Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk Not applicable.

according to Annex II of MARPOL 73/78 and the IBC

Code

General information The transportation information provided represents the regulatory transport classification of the

product without consideration to packaging, quantity, or modal restrictions and exceptions. It is the user's responsibility to determine the appropriate packaging and modal requirements and/or limitations for the product quantity being shipped. It may be eligible for Excepted Quantity

exemption, dependant on quantity of units within the outer package.

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

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

Calcium chloride, dihydrate (CAS 10035-04-8)

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

Sodium azide (CAS 26628-22-8)

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Calcium chloride, dihydrate (CAS 10035-04-8)

Sodium azide (CAS 26628-22-8)

Directive 94/33/EC on the protection of young people at work

Sodium azide (CAS 26628-22-8)

Other regulations This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The

product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation)

as amended and respective national laws implementing EC directives.

Young people under 18 years old are not allowed to work with this product according to the EU

Directive 94/33/EC on the protection of young people at work.

National regulationsThe product has been classified according to the legislation in force.

15.2. Chemical safety

assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

LD50: Lethal Dose, 50%.

References IARC Monographs. Overall Evaluation of Carcinogenicity

HSDB (2005)

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

H300 Fatal if swallowed.

H310 Fatal in contact with skin. H315 Causes skin irritation. H319 Causes serious eye irritation.

H335 May cause respiratory irritation. H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Training information Disclaimer

Follow training instructions when handling this material.

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 BioMedica 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 BioMedica Diagnostics has been advised of the possibility of such damages.