

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name or designation of the mixture	Assay Buffer
Registration number	-
Synonyms	None.
Product code	10X Assay Buffer, in 846 ACTICHROME® TF
Issue date	01-December-2017
Version number	02
Revision date	19-July-2017
Supersedes date	03-June-2015

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

Identified uses	Assorted.
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
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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

This preparation is not classified as dangerous according to Directive 1999/45/EC and its amendments.

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

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended**Contains:** Tris-(hydroxymethyl)aminomethane**Hazard pictograms****Signal word** Warning**Hazard statements**H315 Causes skin irritation.
H319 Causes serious eye irritation.**Precautionary statements****Prevention**P264 Wash thoroughly after handling.
P280 Wear protective gloves/eye protection/face protection.**Response**P302 + P352 IF ON SKIN: Wash with plenty of water.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P362 Take off contaminated clothing and wash 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.**Storage**

Store away from incompatible materials.

Disposal

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

Supplemental label information Not applicable.**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
Tris-(hydroxymethyl)aminomethane	10 - < 20	77-86-1 201-064-4	-	-	
Classification:	DSD: Xi;R36/37/38				
	CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				
Sodium chloride	3 - 8	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	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. May cause redness and pain.
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 (CO ₂).
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. Wear appropriate protective equipment and clothing during clean-up.
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.
6.3. Methods and material for containment and cleaning up	Absorb spill with vermiculite or other inert material. 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 contact with skin and eyes. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
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. Keep container tightly closed.
7.3. Specific end use(s)	Assorted.

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	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
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	
- Hand protection	Wear appropriate chemical resistant gloves.

- Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment.
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

Physical state	Liquid.
Form	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	8.5
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)	Not available.
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 Not 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	Vapours may irritate throat and respiratory system and cause coughing.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.

Ingestion	Harmful 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 Harmful if swallowed.

Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 10000 mg/kg
<i>Oral</i>		
LD50	Rat	> 3980 mg/kg
<i>Other</i>		
LD50	Mouse	2602 mg/kg
Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)		
Acute		
<i>Oral</i>		
LD50	Rat	5900 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory sensitisation	Not classified.	
Skin sensitisation	Not a skin sensitiser.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
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	No other specific acute or chronic health impact noted.	

SECTION 12: Ecological information

12.1. Toxicity

Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
Aquatic		
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 Not available.

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 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 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable 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.
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used.
Disposal methods/information	Dispose in accordance with all applicable regulations. This 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

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 as amended. 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

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

R36/37/38 Irritating to eyes, respiratory system and 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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