

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	Assay buffer in 813 & 813RUO
Issue date	01-December-2017
Version number	02
Revision date	14-July-2017
Supersedes date	14-July-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
 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

Serious eye damage/eye irritation	Category 1	H318 - Causes serious eye damage.
-----------------------------------	------------	-----------------------------------

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 3	H412 - Harmful to aquatic life with long lasting effects.
--	------------	---

Hazard summary Causes serious eye damage.

2.2. Label elements

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

Contains: Ethylenediaminetetraacetic acid trisodium salt, Polyethylene glycol octylphenol ether

Hazard pictograms



Signal word Danger

Hazard statements

H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements**Prevention**

P280 Wear protective gloves/eye protection/face protection.
P273 Avoid release to the environment.

Response

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

Storage

Store away from incompatible materials.

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	30 - 35	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification:	-				
Ethylenediaminetetraacetic acid trisodium salt	10 - 15	85715-60-2 -	-	-	
Classification:	Eye Irrit. 2;H319				
Disodium hydrogen orthophosphate	5 - 10	7558-79-4 231-448-7	-	-	
Classification:	Eye Irrit. 2;H319				
Polyethylene glycol octylphenol ether	3 - 6	9002-93-1 -	-	-	
Classification:	Acute Tox. 4;H302, Eye Dam. 1;H318, Aquatic Chronic 2;H411				

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 H-statements 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.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.
Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact Flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Causes serious eye damage. Dust may irritate skin and the respiratory system. Headaches, nausea and vomiting. Dermatitis.

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 Will burn if involved in a fire.

5.1. Extinguishing media	
Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.
5.2. Special hazards arising from the substance or mixture	Fire will generate toxic and irritating gases.
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	Keep unnecessary personnel away. See Section 8 of the SDS for Personal Protective Equipment.
For emergency responders	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 dust formation. Sweep or scoop up and remove.
6.4. Reference to other sections	For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Persons susceptible for allergic reactions should not handle this product. Observe good laboratory hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2 - 8°C. Store in a closed container away from incompatible materials.
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	No special ventilation requirements.
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 dust-resistant safety goggles.
Skin protection	
- Hand protection	Wear protective gloves. Chemical resistant gloves are recommended.
- Other	It is a good industrial hygiene practice to minimise skin contact.
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.
Form	Powder.
Colour	White.
Odour	None.
Odour threshold	Not applicable.
pH	7.4
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)	Non flammable.
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 explosive.
Oxidizing properties	Not oxidising.
9.2. Other information	
Percent volatile	Not available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Causes serious eye damage.
Ingestion	May cause discomfort if swallowed.
Symptoms	Causes serious eye damage. Dust may irritate skin and the respiratory system. Headaches, nausea and vomiting. Dermatitis.

11.1. Information on toxicological effects

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

Components	Species	Test results
Polyethylene glycol octylphenol ether (CAS 9002-93-1)		
Acute		
<i>Oral</i>		
LD50	Rat	1800 mg/kg
Skin corrosion/irritation	Dust may irritate skin.	
Serious eye damage/eye irritation	Causes serious eye damage.	
Respiratory sensitisation	Not classified.	
Skin sensitisation	Not classified. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals.	
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 Harmful to aquatic life with long lasting effects.

Components	Species	Test results
Polyethylene glycol octylphenol ether (CAS 9002-93-1)		
Aquatic		
Crustacea	LC50 Water flea (Daphnia magna)	7.5 - 9.8 mg/l, 48 hours
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

Polyethylene glycol octylphenol ether (CAS 9002-93-1)

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Polyethylene glycol octylphenol ether (CAS 9002-93-1)

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

H302 Harmful if swallowed.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Training information

Follow training instructions when handling this material.

Disclaimer

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.