

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

### 1.1. Product identifier

Trade name or designation of the mixture	Enzyme Conjugate Diluent
Registration number	-
Synonyms	None.
Product code	899ECD R19, 821ECD, 894ECD
Issue date	01-December-2017
Version number	02
Revision date	18-July-2017
Supersedes date	28-May-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.
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##### Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 3	H412 - Harmful to aquatic life with long lasting effects.
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**Hazard summary** Causes serious eye damage.

### 2.2. Label elements

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

**Contains:** 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** EUH208 - Contains Gentamicin sulfate. May produce an allergic reaction.

**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
Disodium hydrogen orthophosphate	3 - 7	7558-79-4 231-448-7	-	-	
<b>Classification:</b>	Eye Irrit. 2;H319				
Polyethylene glycol octylphenol ether	3 - 6	9002-93-1 -	-	-	
<b>Classification:</b>	Acute Tox. 4;H302, Eye Dam. 1;H318, Aquatic Chronic 2;H411				
Gentamicin sulfate	0.1 - 0.5	1405-41-0 215-778-9	-	-	
<b>Classification:</b>	Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Resp. Sens. 1;H334				

**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.

### 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** Contact with this material can cause irritation to the skin, eyes and mucous membranes. 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.

<b>5.2. Special hazards arising from the substance or mixture</b>	Fire will generate toxic and irritating gases.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	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.
<b>Special fire fighting procedures</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	Keep unnecessary personnel away. See Section 8 of the SDS for Personal Protective Equipment.
<b>For emergency responders</b>	Use personal protection recommended in Section 8 of the SDS.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	Avoid dust formation. Sweep or scoop up and remove.
<b>6.4. Reference to other sections</b>	For waste disposal, see Section 13 of the SDS.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Avoid prolonged exposure. Persons susceptible for allergic reactions should not handle this product. Observe good laboratory hygiene practices.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store at 2 - 8°C. Store in a closed container away from incompatible materials.
<b>7.3. Specific end use(s)</b>	Assorted.

## SECTION 8: Exposure controls/personal protection

<b>8.1. Control parameters</b>	
<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Recommended monitoring procedures</b>	Follow standard monitoring procedures.
<b>Derived no-effect level (DNEL)</b>	Not available.
<b>Predicted no effect concentrations (PNECs)</b>	Not available.
<b>Exposure guidelines</b>	Follow standard monitoring procedures.
<b>8.2. Exposure controls</b>	
<b>Appropriate engineering controls</b>	No special ventilation requirements.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>General information</b>	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
<b>Eye/face protection</b>	Wear dust-resistant safety goggles.
<b>Skin protection</b>	
- <b>Hand protection</b>	Wear protective gloves. Chemical resistant gloves are recommended.
- <b>Other</b>	It is a good industrial hygiene practice to minimise skin contact.
<b>Respiratory protection</b>	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	Handle in accordance with good industrial hygiene and safety practices.
<b>Environmental exposure controls</b>	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

<b>Appearance</b>	White powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.

<b>Colour</b>	White.
<b>Odour</b>	None.
<b>Odour threshold</b>	Not applicable.
<b>pH</b>	7.2
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not relevant.
<b>Flash point</b>	Not relevant.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Non flammable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not relevant.
<b>Vapour density</b>	Not relevant.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Soluble in water.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not relevant.
<b>Explosive properties</b>	Not relevant.
<b>Oxidizing properties</b>	Not oxidising.
<b>9.2. Other information</b>	
<b>Percent volatile</b>	Not relevant.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	Stable at normal conditions.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	Polymerization will not occur.
<b>10.4. Conditions to avoid</b>	Keep away from heat.
<b>10.5. Incompatible materials</b>	Strong oxidising agents. Strong reducing agents. Strong acids.
<b>10.6. Hazardous decomposition products</b>	Carbon oxides. Nitrogen oxides. Potassium oxides.

## SECTION 11: Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Dust may irritate respiratory system.
<b>Skin contact</b>	Dust may irritate skin.
<b>Eye contact</b>	Causes serious eye damage.
<b>Ingestion</b>	May cause discomfort if swallowed.

**Symptoms** Contact with this material can cause irritation to the skin, eyes and mucous membranes. Headaches, nausea and vomiting. Dermatitis.

### 11.1. Information on toxicological effects

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

<b>Components</b>	<b>Species</b>	<b>Test results</b>
Polyethylene glycol octylphenol ether (CAS 9002-93-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1800 mg/kg

<b>Skin corrosion/irritation</b>	Dust may irritate skin.
<b>Serious eye damage/eye irritation</b>	Causes serious eye damage.
<b>Respiratory sensitisation</b>	Not classified.
<b>Skin sensitisation</b>	Not classified.
<b>Germ cell mutagenicity</b>	Not classified.
<b>Carcinogenicity</b>	Not classified.
<b>Reproductive toxicity</b>	Not classified.
<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not classified.
<b>Mixture versus substance information</b>	Not available.
<b>Other information</b>	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)		
<b>Aquatic</b>		
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

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.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H411 Toxic to aquatic life with long lasting effects.

**Training information**

Follow training instructions when handling this material.

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