

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

1.1. Product identifier

Trade name or designation of the mixture	840 R3: PTA Reagent
Registration number	-
Synonyms	None.
Product code	840 R3, component of kit: 840 ACTICLOT Protein C Resistance
Issue date	01-December-2017
Version number	02
Revision date	18-July-2017
Supersedes date	14-September-2016

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

Identified uses	For In Vitro Diagnostic use.
Uses advised against	None known.

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

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.
Acute toxicity, inhalation	Category 4	H332 - Harmful if inhaled.
Specific target organ toxicity - repeated exposure	Category 2 (Respiratory tract)	H373 - May cause damage to organs (Respiratory tract) through prolonged or repeated exposure.

Hazard summary Harmful if inhaled. Harmful if swallowed. May cause damage to organs through prolonged or repeated exposure. Exposure to powder or dusts may be irritating to eyes, nose and throat.

2.2. Label elements

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

Contains: Albumins, blood serum, Disodium dihydrogen ethylenediaminetetraacetate

Hazard pictograms



Signal word Warning

Hazard statements

H302	Harmful if swallowed.
H332	Harmful if inhaled.
H373	May cause damage to organs (Respiratory tract) through prolonged or repeated exposure.

Precautionary statements

Prevention

P260	Do not breathe 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.

Response

P301 + P312	IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
P330	Rinse mouth.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTRE/doctor if you feel unwell.

Storage

Store away from incompatible materials.

Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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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
Albumins, blood serum	25 - 50	9048-46-8 232-936-2	-	-	
Classification:	Acute Tox. 4;H302				
Disodium dihydrogen ethylenediaminetetraacetate	25 - 50	139-33-3 205-358-3	01-2119486775-20-0001	-	
Classification:	Acute Tox. 4;H332, STOT RE 2;H373				

Composition comments The full text for all H-statements is displayed in section 16. 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 If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

4.1. Description of first aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Call a POISON CENTRE or doctor/physician if you feel unwell.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Dusts may irritate the respiratory tract, skin and eyes. Prolonged exposure may cause chronic effects.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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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	Move containers from fire area if you can do so without risk.
Specific methods	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. Do not breathe 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. This product is miscible in water. 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. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

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 Minimise dust generation and accumulation. Do not breathe dust. Do not taste or swallow. When using, do not eat, drink or smoke. Use only outdoors or in a well-ventilated area. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see section 10 of the SDS).

7.3. Specific end use(s) For in vitro diagnostic use.

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 levels (DNELs)

General Population

Components	Value	Assessment factor	Notes
Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)			
Long-term, Local, Inhalation	0.6 mg/m ³	20	
Long-term, Systemic, Oral	25 mg/kg		
Short-term, Local, Inhalation	1.2 mg/m ³		

Workers

Components	Value	Assessment factor	Notes
Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)			
Long-term, Local, Inhalation	1.5 mg/m ³		
Short-term, Local, Inhalation	3 mg/m ³		

Predicted no effect concentrations (PNECs)

Components	Value	Assessment factor	Notes
Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)			
Freshwater	2.2 mg/l	10	
Intermittent releases	1.2 mg/l	100	
Marine water	0.22 mg/l	100	
STP	43 mg/l	10	

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.

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 glasses with side shields (or goggles).

Skin protection

- Hand protection

Wear appropriate chemical resistant gloves.

- Other

Wear suitable protective clothing.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

Keep away from food and drink. 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

Physical state

Solid.

Form

Solid. Lyophilised powder.

Colour

White.

Odour

Not determined.

Odour threshold

Not determined.

pH

7.4 - 7.6

Melting point/freezing point

Not determined.

Initial boiling point and boiling range

Not determined.

Flash point

Not applicable.

Evaporation rate

Not applicable.

Flammability (solid, gas)

Not determined.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not determined.

Flammability limit - upper (%)

Not determined.

Vapour pressure

Not applicable.

Vapour density

Not determined.

Relative density

Not determined.

Solubility(ies)

Not determined.

Partition coefficient (n-octanol/water)

Not applicable.

Auto-ignition temperature

Does not ignite.

Decomposition temperature

Not determined.

Viscosity

Not applicable.

Explosive properties	Product does not present an explosion hazard under normal conditions of use.
Oxidising properties	Not determined.
9.2. Other information	
VOC	Not determined.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and 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	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Inhalation	Harmful if inhaled. May cause damage to organs through prolonged or repeated exposure by inhalation.
Skin contact	Dust or powder may irritate the skin.
Eye contact	Dust may irritate the eyes.
Ingestion	Harmful if swallowed.

Symptoms Dusts may irritate the respiratory tract, skin and eyes.

11.1. Information on toxicological effects

Acute toxicity Harmful if inhaled. Harmful if swallowed.

Components	Species	Test results
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Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)

Acute

Oral

LD50	Rat	2800 mg/kg
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Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory sensitisation Based on available data, the classification criteria are not met.

Skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure May cause damage to organs (Respiratory tract) through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

Mixture versus substance information No information available.

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

SECTION 12: Ecological information

12.1. Toxicity Due to partial or complete lack of data the classification for hazardous to the aquatic environment, is not possible.

Components	Species	Test results
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Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)

Aquatic

Acute

Crustacea	EC50	Daphnia magna	140 mg/l, 48 hours
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12.2. Persistence and degradability	No data is available on the degradability of this product.
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	No data available.
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 of in accordance with local 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	Since emptied containers may retain product residue, follow label warnings even after container is emptied. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of Marpol 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 (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 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 authorisation, 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.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations

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

PBT: Persistent, bioaccumulative and toxic.
vPvB: Very Persistent and very Bioaccumulative.
DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

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

H302 Harmful if swallowed.
H332 Harmful if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.

Training information

Follow training instructions when handling this material.

Disclaimer

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