


1. Identification

Product identifier	840 R3: PTA Reagent	
Other means of identification		
Product code	840 R3, component of kit: 840 ACTICLOT Protein C Resistance	
Recommended use	For In Vitro Diagnostic use.	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Corporate Headquarters	BioMedica Diagnostics Inc. 94 Wentworth Road, PO Box 1030 Windsor, Nova Scotia CANADA B0N 2T0	
7 cbHJWidYfgcb	Corporate Phone: 1-902-798-5105 Corporate Fax: 1-902-798-1025 Email: info@biomedicadiagnostics.com Website: www.biomedicadiagnostics.com	
9a Yf[YbWriHY Yd\ cbY Bi a VYfg	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	
7 cbHfUWibi a VYf	MIS9591327	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Acute toxicity, inhalation	Category 4
	Specific target organ toxicity, repeated exposure	Category 2 (Respiratory Tract)
OSHA defined hazards	Not classified.	
Label elements		

Signal word	Warning
Hazard statement	Harmful if swallowed. Harmful if inhaled. May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Do not breathe dust. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Albumins, blood serum	9048-46-8	25 - 50
Disodium dihydrogen ethylenediaminetetraacetate	139-33-3	25 - 50

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

4. 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 CENTER 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.
Most important symptoms/effects, acute and delayed	Dusts may irritate the respiratory tract, skin and eyes. Prolonged exposure may cause chronic effects.
Indication of 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.
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.

5. Fire-fighting measures

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.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	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.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials 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.
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Minimize 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.
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).

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
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	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Skin protection	
Other	Wear suitable protective clothing.
Respiratory protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Solid. Lyophilised powder.
Color	White.
Odor	Not determined.
Odor 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.
Vapor pressure	Not applicable.
Vapor density	Not determined.
Relative density	Not determined.
Solubility(ies)	
Solubility (water)	Not determined.

Partition coefficient (n-octanol/water)	Not applicable.
Auto-ignition temperature	Does not ignite.
Decomposition temperature	Not determined.
Viscosity	Not applicable.
Other information	
Explosive properties	Product does not present an explosion hazard under normal conditions of use.
Oxidizing properties	Not determined.
VOC	Not determined.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics
Dusts may irritate the respiratory tract, skin and eyes.

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 Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	May cause damage to organs through prolonged or repeated exposure.
Further information	No other specific acute or chronic health impact noted.

12. Ecological information

Ecotoxicity 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.

Components	Species	Test Results
Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50 Daphnia magna	140 mg/l, 48 hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	No data available.	

13. Disposal considerations

Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-December-2017
Revision date 18-July-2017
Version # 02

HMIS® ratings

Health: 2*
Flammability: 0
Physical hazard: 0

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