BTA TRAK® Kit

Section 1 Identification	
Product name	BTA TRAK® Kit
Catalog number	662150, 662160 (export only)
Recommended use	Quantitative test for recurrent bladder cancer in human urine
Manufactured by	Polymedco Cancer Diagnostic Products, LLC. 510 Furnace Dock Road Cortlandt Manor, NY 10567 www.polymedco.com
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Wash Buffer (20X):	
Hazard classification	Acute toxicity, oral – Category 3 Acute toxicity, dermal – Category 3 Hazardous to the aquatic environment, short-term hazard – Category 3 Hazardous to the aquatic environment, long-term hazard – Category 3
Signal word	Danger
Pictogram	
Hazard statements	H301 Toxic if swallowed. H311Toxic in contact with skin. H402 Harmful to aquatic life. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	P264 Wash hands thoroughly after handling. P270 Do not eat, drink, or smoke when using this product. P273 Avoid release into the environment. P280 Wear protective gloves / protective clothing. P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P330 Rinse mouth. P302 + P352 IF ON SKIN: Wash with plenty of water P312 Call a POISON CENTER / doctor if you feel unwell. P361 + P364 Take off immediately all contaminated clothing and wash it before reuse P405 Store locked up. P501 Dispose of contents/container in accordance with local, regional, and national regulations.
Substrate Tablets:	
Hazard classification	Does not present any particular health hazard.
Signal word	None
Pictogram	None
Hazard statements	None
Precautionary statements	None

Section 2 Hazards Identification (cont.)	
Substrate Buffer:	
Hazard classification	Specific target organ toxicity, repeated exposure – Category 2 Serious eye damage / eye irritation – Category 2B
Signal word	Warning
Pictogram	
Hazard statements	H373 May cause damage to organs through prolonged or repeated exposure. H320 Causes eye irritation.
Precautionary statements	P260 Do not breathe dust/fume/gas/mist/vapours/spray. P264 Wash hands thoroughly after handling. P314 Get medical advice/attention if you feel unwell. 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.
Assay Diluent, Stop Reagent, Enzyme Tracer, Calibrators and Controls:	
Hazard classification	Acute toxicity, oral – Category 4 Hazardous to the aquatic environment, long-term hazard – Category 3
Signal word	Warning
Pictogram	
Hazard statements	H302 Harmful if swallowed. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	P264 Wash hands thoroughly after handling. P270 Do not eat, drink, or smoke when using this product. P273 Avoid release into the environment. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor / physician if you feel unwell. P330 Rinse mouth. P501 Dispose of contents/container in accordance with local, regional, and national regulations.
Any hazards not otherwise classified	Controls and calibrators contain materials derived from human source material that has been tested and found negative for Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus (HCV) antibody. FDA approved methods have been used to conduct these tests. No test can offer complete assurance that infectious agents are absent, so handle this product as potentially biohazardous material.

Section 3 Composition and Information on Ingredients			
Wash Buffer (20X):			
Chemical characterization	Contains Tween® 20 and sodium azide		
Chemical name	Tween® 20	Sodium Azide	
Synonyms	Polyoxyethylenesorbitan monolaurate	Azium	
CAS number	9005-64-5	26628-22-8	
Concentration	2%	2%	
Substrate Buffer:			
Chemical characterization	Contains diethanolamine		
Chemical name	Diethanolamine		
Synonyms	Bis(2-hydroxyethyl)amine, 2,2′-Iminodiethanol		
CAS number	111-42-2		
Concentration	11%		
Enzyme Tracer and Assay Diluent:			
Chemical characterization	Contain zinc chloride and sodium azide		
Chemical name	Zinc Chloride	Sodium Azide	
Synonyms	None	Azium	
CAS number	7646-85-7	26628-22-8	
Concentration	<0.1%	0.1%	
Stop Reagent:			
Chemical characterization	Contains EDTA and sodium azide		
Chemical name	EDTA	Sodium Azide	
Synonyms	Ethylenediaminetetraacetic acid	Azium	
CAS number	6381-92-6	26628-22-8	
Concentration	0.4%	0.1%	
Controls and Calibrators:			
Chemical characterization	Contain zinc chloride, tartrazine, and sodium azide		
Chemical name	Zinc Chloride	Tartrazine	Sodium Azide
Synonyms	None	Acid Yellow 23	Azium
CAS number	7646-85-7	1934-21-0	26628-22-8
Concentration	<0.1%	<0.1%	0.1%
Substrate Tablets:			
Chemical characterization	p-Nitrophenyl phosphate tablets		
Chemical name	p-Nitrophenyl phosphate		
Synonyms	4-Nitrophenyl phosphate disodium salt hexahydrate		
CAS number	33338-18-4		
Concentration	5 mg		

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. Call a POISON CENTER / doctor if you feel unwell.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

Section 5 Fire-Fighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire
Special fire and explosion hazards	No special hazards determined
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters

Section 6 Accident Release Measures	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill. Decontaminate spill area with bleach or other suitable disinfectant.

Section 7 Handling and Storage	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	2 - 8°C
Incompatibilities	Not determined

Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Diethanolamine: 15 mg/m^3
ACGIH	Sodium azide: 0.29 mg/m^3 Diethanolamine: 1 mg/m^3
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

Section 9 Physical and Chemical Properties							
	Wash Buffer	**Substrate Buffer**	**Enzyme Tracer**	**Assay Diluent**	**Stop Reagent**	**Controls and Calibrators**	**Substrate Tablets**
Appearance	Clear colorless solution	Clear colorless solution	Clear colorless solution	Clear colorless solution	Clear colorless solution	Clear green solution	Yellow tablets
Odor	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless
Odor threshold	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined
pH	8.0 – 8.2	9.7 – 9.9	5.9 – 6.1	7.3 – 7.5	9.6 – 10.0	7.3 – 7.5	Not available
Melting point / Freezing point	Approx. 0°C	Approx. 0°C	Approx. 0°C	Approx. 0°C	Approx. 0°C	Approx. 0°C	>300°C
Initial boiling point and boiling range	Approx. 100°C	Approx. 100°C	Approx. 100°C	Approx. 100°C	Approx. 100°C	Approx. 100°C	Not applicable
Flash point	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not available
Evaporation rate	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not applicable
Flammability (solid, gas)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not available
Upper/lower flammability or explosive limits	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not available
Vapor pressure	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not applicable
Vapor density	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not applicable
Relative density	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not available
Solubility	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water
Partition coefficient	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not available
Auto-ignition temperature	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not available
Decomposition temperature	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not available
Viscosity	Not determined	Not determined	Not determined	Not determined	Not determined	Not determined	Not applicable

Section 10 Stability and Reactivity	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	None identified
Hazardous reactions	Sodium azide may form explosive azides in contact with strong acids or metals over time.
Hazardous polymerization	Will not polymerize
Incompatibilities	Sodium azide: Strong acids, metals Diethanolamine: Oxidizing agents, copper, zinc, iron
Hazard decomposition products	Not determined
Conditions to avoid	Avoid contact with strong acids. Do not dispose of product into drains.

Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	Not determined
Ingestion	Wash Buffer: Toxic if swallowed All other liquid components: Harmful if swallowed
Skin contact	Wash Buffer: Toxic in contact with skin Substrate Buffer: Possible liver / kidney damage with repeated exposure.
Eye contact	Substrate Buffer: Causes eye irritation
Toxicity (LD50/LC50)	Oral LD50 for sodium azide: Rabbit: 10 mg/kg, Rat: 27 mg/kg Dermal LD50 for sodium azide: Rabbit: 20 mg/kg Oral LD50 for diethanolamine: Rat: 710 mg/kg
Sensitization	Not available
Carcinogenicity	Diethanolamine: IARC group 2B – Possibly carcinogenic to humans
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Sodium Azide: Positive

Section 12 Ecological Information	
Ecotoxicity	Sodium azide: EC50 - Daphnia pulex 4.2 mg/L 48 h Diethanolamine: LC50 – Pimephales promelas 1460 mg/L 96 h Diethanolamine: EC50 – Daphnia magna 55 mg/L 48 h
Persistence / degradability	Diethanolamine: Readily biodegradable (>90%)
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

Section 13 Disposal Considerations	
Disposal containers	Leak-proof containers. Controls and calibrators should be disposed of in containers marked with biohazard symbol.
Disposal methods	Dispose as hazardous waste. Dispose of human source materials in biohazardous or medical waste. Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Contact a licensed professional waste disposal service to dispose of this material. Controls and calibrators are potentially biohazardous material; dispose in biohazardous or medical waste.
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Section 14 Transport Information		
	Sodium azide	Diethanolamine
UN Number	1687	3077
UN proper shipping name	Sodium azide	Diethanolamine
Transport hazard class	6.1	9
Packing group	II	III
Reportable Quanitity	RQ 1000 lbs	RQ 100 lbs
Special precautions on transport	No special requirements	No special requirements

Section 15 Regulatory Information	
TSCA	Sodium azide: Listed Diethanolamine: Listed
SARA	
302	Not applicable
311/312	Sodium azide: Acute Health Hazard, Chronic Health Hazard
313	Sodium azide: Reportable above threshold values Diethanolamine: Reportable above threshold values
CA Prop 65	Diethanolamine: Known to the State of California to cause cancer.
Canada DSL/NDSL	Sodium azide: Listed on DSL Diethanolamine: Listed on DSL
EC Number	Sodium azide: 247-852-1 Diethanolamine: 203-868-0
WHMIS Class	D
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

Section 16 Other Information			
NFPA Ratings:		HMIS Ratings:	
Health	3	Health	3
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards	Potential biohazard	Protective Equipment	C
Date of preparation	27 February 2015		
Last revision date	27 February 2015		
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