




FOBT-CHEK® Control Kit

Section 1 Identification	
Product name	FOBT-CHEK® Control Kit
Catalog number	FBT-POC, FBT-POC-CH
Recommended use	Qualitative controls for FOBT testing
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	
Hazard classification	Acute toxicity, oral – Category 4 Skin corrosion / irritation – Category 2 Serious eye damage / irritation – Category 2B Hazardous to the aquatic environment, long-term hazard – Category 3
Signal word	Warning
Pictogram	
Hazard statements	H302 Harmful if swallowed H315 Causes skin irritation H320 Causes eye irritation 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. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor / physician if you feel unwell. P330 Rinse mouth. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P332 + P313 If skin irritation occurs: Get medical advice / attention. 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. P362 + P364 Take off contaminated clothing and wash it before reuse. P501 Dispose of contents/container in accordance with local, regional, and national regulations.
Any hazards not otherwise classified	This product is 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.



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Section 3 Composition and Information on Ingredients				
Chemical characterization	Controls contain CDTA, sodium molybdate acid, sodium azide Positive control contains human hemoglobin			
Chemical name	CDTA	Sodium Molybdate Dihydrate	Sodium Azide	Human Hemoglobin
Synonyms	Trans-1,2-Diaminocyclohexane-N,N,N',N'-Tetraacetic acid Monohydrate	Molybdic Acid Sodium Dihydrate	Azium	Not applicable
CAS number	125572-95-4	10102-40-6	26628-22-8	9008-02-0
Concentration	1 mM	20 mM	0.1%	0.004% in Positive Control

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. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
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



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Section 8 Exposure Controls and Personal Protection	
Exposure limits:	
OSHA	Not determined
ACGIH	Sodium azide: 0.29 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		
	Positive Control	Negative Control
Appearance	Clear to light tan solution	Clear to light tan solution
Odor	Odorless	Odorless
Odor threshold	Not determined	Not determined
pH	6.2 – 6.6	6.2 – 6.6
Melting point / Freezing point	Approx. 0°C	Approx. 0°C
Initial boiling point and boiling range	Approx. 100°C	Approx. 100°C
Flash point	Not applicable	Not applicable
Evaporation rate	Not determined	Not determined
Flammability (solid, gas)	Not applicable	Not applicable
Upper/lower flammability or explosive limits	Not applicable	Not applicable
Vapor pressure	Not determined	Not determined
Vapor density	Not determined	Not determined
Relative density	Not determined	Not determined
Solubility	Soluble in water	Soluble in water
Partition coefficient	Not determined	Not determined
Auto-ignition temperature	Not determined	Not determined
Decomposition temperature	Not determined	Not determined
Viscosity	Not determined	Not determined

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	Strong acids; metals
Hazard decomposition products	Not determined
Conditions to avoid	Avoid contact with strong acids. Do not dispose of product into drains.



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Section 11 Toxicological Information	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	Not determined
Ingestion	Harmful if swallowed
Skin contact	Causes skin irritation
Eye contact	Causes eye irritation
Toxicity (LD50/LC50)	Oral LD50 for sodium azide: Rabbit: 10 mg/kg, Rat: 27 mg/kg Intraperitoneal for sodium molybdate: Rat: 520 mg/kg
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Sodium Azide: Positive

Section 12 Ecological Information	
Ecotoxicity	Long term hazard to aquatic environment
Persistence / degradability	Not determined
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	Controls: Leak-proof container marked with biohazard symbol.
Disposal methods	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	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	Dispose in biohazardous or medical waste

Section 14 Transport Information	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified



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Section 15 Regulatory Information	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Sodium azide: Listed on DSL
WHMIS Class	Sodium azide: Not controlled below 1%
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	1	Health	1
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards	Potential biohazard	Protective Equipment	B
Date of preparation	24 September 2014		
Last revision date	26 February 2015		
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