SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Identifier

Product Name(s):	Immunoassay Control levels 1, 2, 3 and Tri-Level
Product Code(s):	94101, 94102, 94103, 94104 and 94109
Synonyms:	None
Intended Use	An assayed quality control material for In Vitro Diagnostic Use
Manufacturer Name:	Cliniqa Corporation
Address:	288 Distribution Street San Marcos, CA 92078 USA www.cliniqa.com
Cliniqa Corporation:	(800) 728-5205 or (760) 744-1900 **(Pacific Day Time)**
Emergency Phone:	United States Center Centers for Disease Control and Prevention 800-CDC-INFO (800-232-4636) or (404) 633-5313 **(24 Hours)**
Authorized Representative in the European Community:	CEpartner4U ESDOORNLAAN 13 3951DB MAARN THE NETHERLANDS www.cepartner4u.eu
SDS Revision Date:	June 1, 2015
SDS Document No.:	50061 SDS
SDS Revision No.:	01

SECTION 2: HAZARDS IDENTIFICATION

Classification is made according to Globally Harmonized System (GHS)-US and EU

Hazardous Classification:	Mixture according to EC regulation No.1272/2008, and 1999/45/EC
Acute Toxicity	Category 3

Label Elements

In compliance with Globally Harmonized System (GHS)-US and EU

Signal Word:	Danger
Pictograms:	
Product Identifiers	EC #200-659-6 Methanol
Hazardous Statement(s):	H301, Toxic if swallowed H331, Toxic if inhaled H311, Toxic in contact with skin
Precautionary Statement-Prevention:	P264, Wash hands thoroughly after handling P270, Do not eat, drink, or smoke while using this product

SECTION 2: HAZARDS IDENTIFICATION

	P261, Avoid breathing mist/vapors/spray. P271, Use only outdoors or in a well-ventilated area. P280, Wear protective gloves/protective clothing/eye protection/face protection
Precautionary statements-Response	P301 + P310, if swallowed, immediately call a Poison Center or doctor/physician P330, Rinse mouth P304+P340, IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P311, Call a POISON CENTER or doctor/physician. P302+P352, IF ON SKIN: Wash with plenty of soap and water. P312, Call a POISON CENTER or doctor/physician if you feel unwell. P361, Remove/Take off immediately all contaminated clothing. P363, Wash contaminated clothing before reuse.
Precautionary statements-Storage	P405, Store locked up. P403+P233, Store in a well-ventilated place. Keep container tightly closed.
Precautionary statements-Disposal	P501, Disposal must be in accordance with appropriate US, Federal, State and International regulations
Special Hazardous:	Contains human sourced material. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Consider all blood derivatives potentially infectious.
NFPA Rating (Scale 0-4):	Health = 0 Fire =0 Reactivity =0
PBT assessments:	Not applicable
vPvB assessment	Not applicable
Other Hazards:	Not applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Characterization: Mixture

Identification	Name	%
CAS #: 67-56-1 **EC#: 200-659-6**	Methanol	<1%
CAS #: N/A **EC#:** N/A	Human Source Material	10-60%

Exposure Limits: Not applicable

SECTION 4: FIRST AID MEASURES

General Information	Use universal precautions. Seek medical attention in case of doubt or if symptoms persist.
Eye Contact:	Rinse immediately with plenty of water for several minutes and seek medical attention.
Ingestion:	Seek medical attention immediately and show the label.

SECTION 4: FIRST AID MEASURES

Inhalation: Supply fresh air immediately. Seek medical attention if breathing difficulty occurs.

Skin Contact: Seek medical attention if symptoms of skin irritation appear.

Protection of First-Aid Providers Wear suitable gloves and eye/face protection.

SECTION 5: FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use an extinguishing media suitable for the surrounding fire.

Unsuitable method of extinguishing: None Known

Special Protective Equipment for Firefighters: Self-contained breathing apparatus and protective suit.

Specific Hazards: No relevant information available.

Hazardous Combustion Products: None known

Explosion Limits

Lower: Unknown
Upper: Unknown

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: Ensure adequate ventilation. Handle as potentially infectious.

Environmental Precautions: Waste disposal must be in accordance with appropriate US, Federal, State and International regulations. Dilute with plenty of water

Methods for Clean Up: Wipe up with adsorbent material. Place in suitable container for prompt disposal. Label the container as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g., a fresh 1:10 dilution of common household bleach.

SECTION 7: HANDLING AND STORAGE

Handling

Technical Measures/Precautions: Wear protective safety glasses, gloves and clothing. Wear disposable gloves while handling reagent. Thoroughly wash hands afterwards.

Storage

Technical Measures/Storage Conditions: Store according to labeling

Incompatible Products: None known

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: None known

Exposure Controls:

Personal protection measures: Use personal protective equipment that is clean and has been properly maintained.

Eye Protection: Wear Safety Glasses

Hand Protection: Wear disposable gloves. Thoroughly wash hands.

Skin and Body Protection: Wear Suitable Protective Clothing, Gloves and Eye/Face.

Respiratory Protection: None required

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Other General Precautions: None required

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Physical State:	Liquid
Color	Straw colored
Odor / Odor Threshold:	Mild odor
pH:	Not relevant
Melting Point / Freezing Point:	Undetermined/Undetermined
Initial Boiling Point and Boiling range:	Undetermined/Undetermined
Flash Point:	Not relevant
Evaporation Rate:	Unknown
Upper/lower Flammability or Explosive Limits:	Unknown
Vapor Pressure:	Not determined
Vapor Density:	Not determined
Relative Density:	Not determined
Solubility(ies):	Not determined
Auto-Ignition:	Product is not self-igniting.
Decomposition Temperature:	Unknown
Viscosity:	Unknown
Other(s):	No other standard characteristics applicable to the identification or hazards of the products are known.

SECTION 10: STABILITY AND REACTIVITY

Reactivity:	No data is available
Chemical Stability:	Stable under recommended storage conditions.
Conditions to Avoid:	Keep away from heat and source of ignition.
Materials to Avoid:	No data available
Hazardous polymerization	Unknown
Hazardous Decomposition Products:	None are known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute effects

Oral:	Toxic if swallowed
Eye contact:	No data available
Skin contact:	Toxic in contact with skin
Inhalation:	Toxic if inhaled

Chronic effects

SECTION 11: TOXICOLOGICAL INFORMATION

Oral: No data available

Inhalation: No data available

Dermal: No data available

Carcinogenicity Rating

Component(s)	CAS Number	NTP:	IARC:	California Proposition 65 List
Butylated Hydroxytoluene	128-37-0	Not listed	3	Not listed
Chloramphenicol	56-75-7	Listed	2A	Not listed
Streptomycin Sulfate	3810-74-0	Not listed	Not rated	Listed
Methanol	67-56-1	Not listed	Not rated	Listed
Hydrochloric Acid,6N,Solution	7647-01-0	Not listed	3	Not listed
Digoxin	020830-75-5	Not listed	2B	Not listed
Progesterone	57-83-0	Listed	Not rated	listed
Estradiol	50-28-2	Not listed	Not rated	listed
Phenytoin sodium	630-93-3	Listed	Not rated	listed

Signs and Symptoms: None are known

Medical Conditions aggravated by Exposure: None are known

SECTION 12: ECOLOGICAL INFORMATION

Eco-Toxicity Effects: This product has no known ecologically toxic effects.

Aquatic Toxicity Effects: No data available

Mobility: No data available

Persistence/degradability: No data available

Biocumulative potential: No data available

Degradation: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste from Residual/Unused Products: Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

Contaminated Packaging: Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

Methods for Clean Up: Wipe up with adsorbent material. Place in suitable container for prompt disposal. Label the container as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g., a fresh 1:10 dilution of common household bleach.

SECTION 14: TRANSPORT INFORMATION

SECTION 14: TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO for air transport, IMO/IMDG for sea, ADR for road, RID for rail, or TDG.

SECTION 15: REGULATORY INFORMATION

SARA (311,312) Hazard Class

Immediate Health: No data is available

Delayed Health: No data is available

TSCA inventory List: Not Listed

WHMIS

WHMIS Trade Secret: None

WHMIS Hazard Class: Not Listed

Canada DSL Inventory List: Not Listed

Notes:

1) SARA= Superfund Amendments and the Reauthorization Act.
2) TSCA= Toxic Substance Control Act.
3) WHMIS=Canadian Workplace Hazardous Material Information System.
4) This product has been classified in accordance with the hazards criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by the CPR.

SECTION 16: OTHER INFORMATION

This data sheet contains changes from the previous version in section(s): Updated sections 2 and 3.

Additional Advice: None are Known

SDS Formats:

1) North American Format- U.S. and Canada This Safety Data Sheet were prepared in accordance with OSHA 29 CFR 1910.1200.
2) European Format: This Safety Data Sheet was prepared in accordance with (EC) No 1907/2006 (REACH) and its amendments

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