

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

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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

Precautionary statements-Response	<p>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</p> <p>P301 + P310, if swallowed, immediately call a Poison Center or doctor/physician P321, Specific Treatment, see First Aid Measures. 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. P321, see First Aid Measures P302+P352, IF ON SKIN: Wash with plenty of soap and water. P312, Call a POISON CENTER or doctor/physician if you feel unwell. P322, see First Aid Measures P361, Remove/Take off immediately all contaminated clothing. P363, Wash contaminated clothing before reuse.</p>
Precautionary statements-Storage	<p>P405, Store locked up. P403+P233, Store in a well-ventilated place. Keep container tightly closed. P405, Store locked up</p>
Precautionary statements-Disposal	<p>P501, Disposal must be in accordance with appropriate US, Federal, State and International regulations</p>
Special Hazardous:	<p>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.</p>
NFPA Rating (Scale 0-4):	<p>Health = 0 Fire =0 Reactivity =0</p>
PBT assessments:	<p>Not applicable</p>
vPvB assessment	<p>Not applicable</p>
Other Hazards:	<p>Not applicable</p>

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Characterization: Mixture

Identification	Name	%
CAS #: 67-56-1 EC#: 200-659-6	Methanol	0.10-0.20%
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.
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
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

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, beta;	50-28-2	Not listed	Not rated	listed
5,5-Diphenylhydantoin sod.salt	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

SECTION 13: DISPOSAL CONSIDERATIONS

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

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):

Product first SDS per OSH and EU guideline

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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