

## SAFETY DATA SHEET

### 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:** 495 Enterprise Street  
San Marcos, CA 92078  
USA  
[www.cliniqa.com](http://www.cliniqa.com)

**Cliniqa Corporation:** (800) 728-5205 or (760) 744-1900 (**Pacific Day Time**)

**Emergency Phone:** United States 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](http://www.cepartner4u.eu)

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**SDS Revision No.:** 02

### 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

**Acute Toxicity** Category 5

#### Label Elements

**Signal Word:** Warning

**Pictograms:** Not applicable

**Product Identifiers** EC #200-659-6  
Methanol

**Hazardous Statement(s):** H303, may be harmful if swallowed  
H311, May be harmful if inhaled  
H311, May be harmful in contact with skin

**Precautionary Statement-Prevention:** P264, Wash hands thoroughly after handling  
P270, Do not eat, drink, or smoke while using this product  
P261, Avoid breathing mist/vapors/spray.  
P271, Use only outdoors or in a well-ventilated area.

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### SECTION 2: HAZARDS IDENTIFICATION

<b>Precautionary statements- Response</b>	<p>P280, Wear protective gloves/protective clothing/eye protection/face protection</p> <p>P301 + P312, if swallowed, call a Poison Center or doctor/physician if you feel unwell</p> <p>P330, Rinse mouth</p> <p>P304+P340, IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing</p> <p>P311, Call a POISON CENTER or doctor/physician.</p> <p>P302+P352, IF ON SKIN: Wash with plenty of soap and water.</p> <p>P312, Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P363, Wash contaminated clothing before reuse.</p>
<b>Precautionary statements- Storage</b>	Not applicable
<b>Precautionary statements- Disposal</b>	P501, Disposal must be in accordance with appropriate US, Federal, State and International regulations
<b>Special Hazardous:</b>	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.
<b>NFPA Rating (Scale 0-4):</b>	<p>Health = 0</p> <p>Fire =0</p> <p>Reactivity =0</p>
<b>PBT assessments:</b>	Not applicable
<b>vPvB assessment</b>	Not applicable
<b>Other Hazards:</b>	Not applicable

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical Characterization:** Mixture

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS#	EC #	% Composition
Human source material	N/A	N/A	10-60%
Sodium Azide	26628-22-8	247-852-1	≤ 0.09%
Sodium Hydroxide	1310-73-2	215-185-5	<0.01%
Chloramphenicol	56-75-7	200-287-4	<0.1%
Butylated Hydrotoluene	128-37-0	N/A	<0.1%
Streptomycin Sulfate	3810-74-0	223-286-0	<0.1%
Methanol	67-56-1	200-659-6	≤1%
Hydrochloric Acid, 6N, solution	7647-01-0	231-595-7	<0.01%
Proprietary neutral non-hazardous buffer	N/A	N/A	09-39%

**Exposure Limits:** None known

### SECTION 4: FIRST AID MEASURES

<b>General Information</b>	Use universal precautions. Seek medical attention in case of doubt or if symptoms persist.
<b>Eye Contact:</b>	Rinse immediately with plenty of water for several minutes and seek medical attention.
<b>Ingestion:</b>	Seek medical attention immediately and show the label.
<b>Inhalation:</b>	Supply fresh air immediately. Seek medical attention if breathing difficulty occurs.
<b>Skin Contact:</b>	Seek medical attention if symptoms of skin irritation appear.
<b>Protection of First-Aid Providers</b>	Wear suitable gloves and eye/face protection.

### SECTION 5: FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use an extinguishing media suitable for the surrounding fire.
<b>Unsuitable method of extinguishing:</b>	None Known
<b>Special Protective Equipment for Firefighters:</b>	Self-contained breathing apparatus and protective suit.
<b>Specific Hazards:</b>	No relevant information available.
<b>Hazardous Combustion Products:</b>	None known
<b>Explosion Limits</b>	
	<b>Lower:</b> Unknown
	<b>Upper:</b> Unknown

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### SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Ensure adequate ventilation. Handle as potentially infectious.
<b>Environmental Precautions:</b>	Waste disposal must be in accordance with appropriate US, Federal, State and International regulations. Dilute with plenty of water
<b>Methods for Clean Up:</b>	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.
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#### Storage

Technical Measures/Storage Conditions:	Store according to labeling
Incompatible Products:	None known

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Occupational Exposure Limits:</b>	None known
<b>Exposure Controls:</b>	
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
<b>Other General Precautions:</b>	None required

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### Appearance:

Physical State:	Liquid
Color:	Straw colored

**Odor / Odor Threshold:** Mild odor

**pH:** Not relevant

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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

### SECTION 10: STABILITY AND REACTIVITY

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

### SECTION 11: TOXICOLOGICAL INFORMATION

#### Acute effects

Oral:	May be harmful if swallowed
Eye contact:	No data available
Skin contact:	May be harmful in contact with skin
Inhalation:	May be harmful if inhaled

#### Chronic effects

Oral:	No data available
Inhalation:	No data available
Dermal:	No data available

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**SECTION 11: TOXICOLOGICAL INFORMATION**

**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

**Signs and Symptoms:**

None are known

**SECTION 12: 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 13: REGULATORY INFORMATION**

Description	CAS#	SARA Title III, Section 302	SARA Title III, Section 313	SARA Title III, Section 311/231	Japan Poisonous and Deleterious substances control law
Sodium Azide	26628-22-8	X	X		Poisonous substance
Streptomycin Sulfate	3810-74-0			X	
Methanol	67-56-1			X	Deleterious substances
Hydrochloric Acid 6.0 Solution	7647-01-0	X	X		Deleterious substances
Sodium Hydroxide Solution	1310-73-2				Deleterious substances

**Immediate Health:** No data is available

**Delayed Health:** No data is available

**SVHC:** No component of this product is identified as Substances of Very High Concern by SVHC

**TSCA:** No component of this product is identified by the Toxic Substance Control Act

**OSHA:** No component of this product present at levels identified as a carcinogen or potential carcinogen by OSHA

**WHMIS Trade Secret:** None

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### SECTION 13: REGULATORY INFORMATION

**WHMIS Hazard Class:** Not Listed

**Canada DSL Inventory List:** Not Listed

**Notes:**

- 1) SARA= Superfund Amendments and the Reauthorization Act.
- 2) SVHC=Substances of Very High Concern
- 3) TSCA= Toxic Substance Control Act
- 4) WHMIS 2015=Canadian Workplace Hazardous Material Information System.
- 5) 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.
- 6) OSHA=Occupational Safety and Health Administration

### SECTION 14: OTHER INFORMATION

**This data sheet contains changes from the previous version in section(s):**

Updated sections 1, 2,3,11 and 15

**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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