

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: Cliniqua Corporation

Address: 495 Enterprise Street
San Marcos, CA 92078
USA
www.cliniqua.com

Cliniqua 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)**

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SDS Revision Date: January 9, 2018

SDS Document No.: 50061 SDS

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

	P280, Wear protective gloves/protective clothing/eye protection/face protection
Precautionary statements- Response	P301 + P312, if swallowed, call a Poison Center or doctor/physician if you feel unwell 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. P363, Wash contaminated clothing before reuse.
Precautionary statements- Storage	Not applicable
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

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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

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

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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.
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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

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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:	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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