

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**Product Identifier**

Product Name(s):	LiniCAL® Calibration Verifiers Protein 3 for Roche Systems
Product Code(s):	98503
Synonyms:	None
Intended Use	Calibration Verifiers 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:	August 7, 2015
SDS Document No.:	50160 SDS
SDS Revision No.:	00

SECTION 2: HAZARDS IDENTIFICATION

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

Hazardous Classification: Not applicable according to EC regulation No. 1272/2008 and 1999/45/EC

Label Elements

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

Signal Word:	Not applicable
Pictograms:	Not applicable
Product Identifiers	Not applicable
Hazardous Statement(s):	Not applicable
Precautionary Statement- Prevention:	Not applicable
Precautionary statements- Response	Not applicable
Precautionary statements-Storage	Not applicable
Precautionary statements-Disposal	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

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 #: 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.
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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:	Use personal protective equipment that is clean and has been properly maintained.
Personal protection measures:	Wear Safety Glasses
Eye Protection:	Wear disposable gloves. Thoroughly wash hands.
Hand Protection:	Wear Suitable Protective Clothing, Gloves and Eye/Face.
Skin and Body Protection:	None required
Respiratory Protection:	None required
Other General Precautions:	None known

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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:	No data available
Eye contact:	No data available
Skin contact:	No data available
Inhalation:	No data available

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
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SECTION 11: TOXICOLOGICAL INFORMATION

Hydrochloric Acid, 6N Stock Solution (< 0.1%)	7647-01-0	Not listed	3	Not listed
Chloramphenicol (≤ 0.1%)	56-75-7	Listed	2A	Not listed
Streptomycin Sulfate (≤ 0.1%)	3810-74-0	Not Listed	Not rated	Listed

Signs and Symptoms: None known
Medical Conditions aggravated by Exposure: None 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

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

SECTION 15: REGULATORY INFORMATION**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 GHS requirements

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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