

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

**Product Name(s):** Urine Chemistry Control Bi- Level Kit, Levels 1 and 2  
**Product Code(s):** 97105 and 97109

**Synonyms:** None

**Intended Use** An assayed quality control material for In Vitro Diagnostic Use

**Manufacturer Name:** Cliniqua Corporation

**Address:** 288 Distribution Street  
San Marcos, CA 92078  
USA  
[www.cliniqua.com](http://www.cliniqua.com)

**Cliniqua 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](http://www.cepartner4u.eu)

**SDS Revision Date:** September 3, 2015

**SDS Document No.:** 50181 SDS

**SDS Revision No.:** 00

**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

Skin Irritation: Category 2  
Eye Irritation: Category 2  
Acute Toxicity: Category 3  
Skin Corrosion: Category 1B  
Skin Sensitisers: Category 1  
Eye Damage: Category 1  
Acute Aquatic: Category 1

**Label Elements**

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

**Signal Word:** Danger

**SECTION 2: HAZARDS IDENTIFICATION**

**Pictograms:**



**Product Identifiers**

EC# N/A  
 MES (Monohydrate)  
 EC# 247-500-7  
 PRO-CLEAN 400

**Hazardous Statement(s):**

H315, Causes skin irritation  
 H319, Causes serious eye irritation  
 H301, Toxic if swallowed  
 H311, Toxic in contact with skin  
 H331, Toxic if inhaled  
 H314, Causes severe skin burns and eye damage  
 H334, May cause allergy or asthma symptoms or breathing difficulties if inhaled  
 H318, Causes serious eye damage  
 H400, Very toxic to aquatic life

**Precautionary Statement-Prevention:**

P264, Wash hands thoroughly after handling  
 P280, Wear protective gloves/protective clothing/eye protection/face protection  
 P270, Do not eat, drink, or smoke while using this product  
 P260, Do not breathe mist/vapors/spray  
 P261, Avoid breathing mist/vapors/spray  
 P272, Contaminated work clothing should not be allowed out of the workplace  
 P273, Avoid release to the environment

**Precautionary statements-Response:**

P302+P352, IF ON SKIN: wash with plenty of soap and water  
 P332+P313, If skin irritation occurs: Get medical advice/attention  
 P362, Take off contaminated clothing and wash before reuse  
 P305+P351+P338, IF IN EYES: Rinse cautiously with water for several minutes; Remove contact lenses, if present and easy to do. Continue rinsing  
 P337+P313, If eye irritation persists: Get medical advice/attention  
 P301+P310, if swallowed, immediately call a Poison Center or doctor/physician  
 P330, Rinse mouth  
 P301+P330+P331, IF SWALLOWED: rinse mouth; Do NOT induce vomiting  
 P303+P361+P353, IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing  
 P310, Immediately call a POISON CENTER or

**SECTION 2: HAZARDS IDENTIFICATION**

doctor/physician  
 P363, Wash contaminated clothing before reuse  
 P304+P340, IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
 P305+P351+P338, IF IN EYES: Rinse cautiously with water for several minutes; Remove contact lenses, if present and easy to do; Continue rinsing  
 P391, Collect spillage

**Precautionary statements-Storage:** P405, Store locked up

**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 #: N/A EC#: N/A	Human Source Material	5.0 – 15.0%
CAS #: 145224-94-8 EC#: N/A	MES (Monohydrate)	0.5 – 2.0%
CAS #: 26172-55-4 EC#: 247-500-7	PRO-CLEAN 400	0.05 – 1.0%

**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**

<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

**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
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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****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 known

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****Appearance:**

Physical State: Liquid

Color: Pale yellow to colorless

**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

**SECTION 10: STABILITY AND REACTIVITY**

**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

**Skin Corrosion/Irritation:** Causes skin irritation; Causes severe skin burns and eye damage

**Serious Eye Damage/ Irritation** Causes serious eye irritation; Causes serious eye damage

**Skin Sensitization** May cause allergy or asthma symptoms or breathing difficulties 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
Sulfuric Acid (<1%)	7664-93-9	Listed	1	Not Listed
Chloramphenicol (≤ 0.1%)	56-75-7	Listed	2A	Not Listed
Streptomycin Sulfate (<1%)	3810-74-0	Not Listed	Not Rated	Listed
Hydrochloric Acid, 6N, solution (< 0.1%)	7647-01-0	Not Listed	3	Not Listed
Ethanol, Anhydrous, Denatured	64-17-5	Not Listed	1	Not Listed
Lithium Carbonate	554-13-2	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:** Actue- Very toxic to aquatic life  
**Mobility:** No data available  
**Persistence/degradability:** No data available  
**Biocumulative potential:** No data available

**SECTION 12: ECOLOGICAL INFORMATION**

**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

**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

**SECTION 15: REGULATORY INFORMATION****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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