

Section 1 – Product and Company Identification**1.1 Manufacturer Information**

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1.2 Product Information

Product Name: Swab, UTM (Universal Transport Medium), and VCM (Viruses-Chlamydiae-Mycoplasmas Medium) Sets

Catalog #: Refer to Section 16 for a list of applicable catalog numbers for items covered by this SDS.

Intended Use: The collection and transport of clinical specimens containing viruses, *Chlamydiae*, mycoplasma or ureaplasma from the collection site to the testing laboratory.

Components: UTM + FLOQSwab™¹ (nylon®) “Sets”, UTM + Mattress Swab (polyester fibers) “Sets”, Custom Collection “Sets”, UTM (Universal Transport Medium)

Section 2 – Hazard Identification

2.1 Classification of the Substance of Mixture(s) Not a hazardous substance or mixture.

2.2 GHS Label Elements, including Precautionary Statements Not a hazardous substance or mixture.

2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS

Follow Universal Precautions when working with the components of this kit and patient samples.

Section 3 – Composition / Information on Ingredients**3.1 Mixtures**

Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200).
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

3.2 No chemicals need to be disclosed according to the applicable regulations for the components in this kit.

Section 4 – First Aid Measures**4.1 Description of First Aid Measures**

If inhaled: Move the person to fresh air and support breathing as required.

In case of skin contact: Wash affected area with soap and water. Seek medical advice if irritation develops.

In case of eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified.

¹ FLOQSwab™ by Copan is the trademark of Copan Flock Technologies “flocked” collection devices (formerly known as Microrheologics, Copan Italia S.p.A., Brescia, Italy).

Section 5 – Fire Fighting Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

5.1 Suitable Extinguishing Media

For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising From the Substance or Mixture

Nature of decomposition products not known.

5.3 General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

5.4 Fire Fighting Equipment

Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of the components contained within this kit is unlikely.

6.1 Personal Precautions

Avoid breathing vapors, mist or gas.

6.2 Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

6.3 Methods and Materials for Clean-Up

Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.

6.4 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

Section 7 – Handling and Storage

7.1 Specific Use

For professional use only – Not for use by the general public.

7.2 Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components ON YOU or IN YOU. Wash exposed areas thoroughly after using these components. Do not eat or drink while using these components. The components should be handled only by qualified clinical or laboratory employees trained on the use of these swabs and medium and who are familiar with the potential hazards. **Universal Precautions should be followed when handling and working with these components.** Keep out of reach of the general public.

7.3 Conditions for Safe Storage (including any incompatibilities)

To maintain efficacy, store according to the package insert instructions.

7.4 Incompatibilities

To maintain efficacy, store according to the package insert instructions.

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits

No data available for the transport mediums.

8.2 Exposure Controls

Engineering Measures

Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection

None needed under normal conditions of use.

Skin Protection

Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

Eye Protection

Wear safety glasses with side shields or goggles to prevent eye contact.

Section 8 – Exposure Controls and Personal Protection (cont'd.)

Body Protection Use body protection appropriate for the task. A laboratory coat is recommended.
Hygiene Measures Wash hands before use, after use and at the end of the workday.

8.3 Environmental Exposure Controls No special environmental controls are required.

8.4 Special Notes No data available.

Section 9 – Physical and Chemical Properties

Characteristic	Universal Transport Medium (UTM)	Viruses-Chlamydiae-Mycoplasmas Medium (VCM)
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
pH	7.35	7.3
Solubility in Water	Soluble	Soluble
Appearance and Odor	Red, aqueous liquid; odorless	Light orange, aqueous liquid, odorless

Section 10 – Stability and Reactivity

Characteristic	Universal Transport Medium (UTM)	Viruses-Chlamydiae-Mycoplasmas Medium (VCM)
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	No data available	No data available
Materials to Avoid	No data available	No data available
Hazardous Decomposition Products	No data available	No data available

Section 11 – Toxicological Properties
11.1 Information on Toxicological Effects

Acute Toxicity No data available
 Skin Corrosion / Irritation No data available
 Respiratory or Skin Sensitization No data available
 Generative Cell Mutagenicity No data available
 Carcinogenicity No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.

Section 11 – Toxicological Properties (cont'd.)

Reproductive Toxicity	No data available	
Teratogenicity	No data available	
Specified Target Organ Toxicity		
<u>Single Exposure:</u>	No data available	<u>Repeated Exposure:</u> No data available
Aspiration Hazard	No data available	
Potential Health Effects		
<i>Inhalation:</i>	May cause respiratory tract irritation.	<i>Skin:</i> May cause skin irritation upon contact.
<i>Ingestion:</i>	May be harmful if swallowed.	<i>Eyes:</i> May cause eye irritation.

11.2 Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

11.3 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

Section 12 – Ecological Information

12.1 Toxicity	No data available
12.2 Persistence and Degradability	No data available
12.3 Bioaccumulative Potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB Assessment	No data available
12.6 Other Adverse Effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid disposal to the environment.

Section 13 – Disposal Considerations

13.1 Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the control stocks into drains, water courses or onto the ground.

13.2 Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

14.1 U.S Department of Transportation (DOT)	These items not regulated for transport.
14.2 International Air Transportation Association (IATA)	These items not regulated for transport.
14.3 International Maritime Dangerous Goods (IMDG)	These items not regulated for transport.

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards	None
SARA 302	The following chemicals are subject to reporting levels established by Sara Title III, Section 302: No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313	The following chemicals are subject to reporting levels established by SARA Title III, Section 313: No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.
SARA311/312 Hazards	No SARA hazards.

15.2 State Regulations

The following chemicals appear on one or more of the following state hazardous substance lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
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California Prop 65: This kit does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

15.3 Canadian – WHMIS Ingredient Disclosure List

Chemical Name	CAS #	Minimum Concentration
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15.4 Additional Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Mixture No data available

Chemical Safety Assessment Not completed for the components contained within this kit.

HMIS Kit Classification:

Health Hazard: 0
 Chronic Health Hazard: *
 Flammability: 0
 Physical Hazard: 0

NFPA Kit Classification:

Health Hazard (blue): 0
 Fire Hazard (red): 0
 Reactivity (yellow): 0
 Special Hazards (white): None

**Use Universal Precautions when working with these components and handling patient samples.*

Section 16 – Other Information

Specific Swab, UTM and UVM Information:
UTM + FLOQSwab™² (nylon®) “Sets”

Catalog #	UTM / FLOQSwab™ Set product name:
401C	UTM with Minitip FLOQSwab™ Set [Urethral Minitip FLOQSwab™ (501CS01) with 3-mL UTM (330CHL)]
402C	UTM with Regular FLOQSwab™ Set [Standard FLOQSwab™ (502CS01) with 3-mL UTM (330CHL)]
403C	UTM with Nasopharyngeal FLOQSwab™ Set [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
404C	UTM with Minitip FLOQSwab™ Set [Urethral Minitip FLOQSwab™ (501CS01) with 1-mL UTM (350CHL)]
405C	UTM with Regular FLOQSwab™ Set [Standard FLOQSwab™ (502CS01) with 1-mL UTM (350CHL)]
406C	UTM with Flexible Minitip FLOQSwab™ Set

² FLOQSwab™ by Copan is the trademark of Copan Flock Technologies “flocked” collection devices (formerly known as Microrheologics, Copan Italia S.p.A., Brescia, Italy).

	[Flexible NP Minitip FLOQSwab™ (503CS01) with 1-mL UTM (350CHL)]
407C	UTM with Adult Contoured FLOQSwab™ Set [Adult Midturbinate FLOQSwab™ (380CS01) with 3-mL UTM (330CHL)]
408C	UTM with Pediatric Contoured FLOQSwab™ Set [Pediatric Midturbinate FLOQSwab™ w/ 80mm breakpoint (780CS01) with 3-mL UTM (330CHL)]
409C	UTM with Pediatric Contoured FLOQSwab™ Set [Pediatric Midturbinate FLOQSwab™ w/ 50mm breakpoint (750CS01) with 1-mL UTM (350CHL)]
410C	UTM with Ultra Minitip FLOQSwab™ Set [Ultra minitip FLOQSwab™ (516CS01) with 1-mL UTM (350CHL)]
411C	UTM with Ultra Minitip FLOQSwab™ Set [Ultra minitip FLOQSwab™ (516CS01) with 3-mL UTM (330CHL)]
99-08020	UTM with 2 Flexible Minitip FLOQSwab™s Set [Two (2) Flexible NP Minitip FLOQSwab™s (503CS01) with 3-mL UTM (330CHL)]
99-08021	UTM with FLOQSwab™s (1 Flexible Minitip, 1 Regular) Set [Standard FLOQSwab™ (502CS01) and Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
99-08024	UTM with FLOQSwab™s (2 Regular) Set [Two (2) Standard FLOQSwab™s (502CS01) with 3-mL UTM (330CHL)]
UTM + Mattress Swab (polyester fibers) "Sets"	
Catalog #	UTM / Swab Set product name:
99-08011.v2	Female Collection with UTM Kit [one (1) regular collection (340-012) swab and one (1) cleaning swab with 3-mL UTM (330CHL)]
99-08012.v2	Male Collection with UTM Kit [wire tip urethral swab (340-013) with 3-mL UTM (330CHL)]
99-08013.v2	Unisex Configuration Kit [two (2) regular mattress swabs (340-014) with 3-mL UTM (330CHL)]
303CHL	Combination Swab Set: Male/Female [one (1) regular collection swab (340-012) and one (1) wire tip urethral (340-013) with 3-mL UTM (330CHL)]
Custom Collection "Sets"	
Catalog #	VCM / Swab Set product name:
99-08011-VCM	VCM with Cervical Swab (Quest) [Cervical Swabs (cleaning swab + collection swab) (DHI 99-07011.v2) with 3-mL VCM (455-050)]
99-08013-VCM	VCM with Lesion Swab (Quest) [Package with two (2) Lesion Swabs (DHI 99-07013.v2) with 3-mL VCM (455-050)]
99-08014-VCF	VCM with Urethral FLOQSwab™ (Quest) [Urethral FLOQSwab™ (DHI 99-07012.v3) with 3-mL VCM (455-050)]
99-08015-VCF	VCM with Nasopharyngeal FLOQSwab™ (Quest) [Nasopharyngeal FLOQSwab™ (DHI 99-07011.v2) with 3-mL VCM (455-050)]
99-08018A	UTM with Regular FLOQSwab™ (Sonora) [Standard FLOQSwab™ (502CS01) with 3-mL UTM (330CHL)]
99-08019A	UTM with Flexible Minitip FLOQSwab™ (Sonora) [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
99-08019E	UTM with Flexible Minitip FLOQSwab™ (Erie) [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
401C-A	UTM with Minitip FLOQSwab™ ARUP [Urethral Minitip FLOQSwab™ (501CS01) with 3-mL UTM (330CHL)]
402C-A	UTM with Regular FLOQSwab™ ARUP [Standard FLOQSwab™ (502CS01) with 3-mL UTM (330CHL)]
403C-A	UTM with Nasopharyngeal FLOQSwab™ ARUP [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
403C-B	UTM with Flexible Minitip FLOQSwab™, For Respiratory Virus Testing from NP site only [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
UTM (Universal Transport Medium)	
Catalog #	UTM product name:

330C	3-mL UTM-RT medium in 10-mL size screw cap with conical bottom; each tube contains three 3-mm glass beads
330CHL	beads
350C	1-mL UTM-RT medium in 5-mL size screw cap with conical bottom; each tube contains three 3-mm glass beads
350CHL	beads

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

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SUPERSEDES: April 24, 2015

REVISIONS: Change to 16-section SDS format.

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