



SAFETY DATA SHEET

REVISION DATE: 31 July 2018

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Section 1 – PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Unyvero LRT/Pneumonia Control Panel M404
SYNONYMS: N/A
PRODUCT CODES: M404

USE OF THE SUBSTANCE PREPARATION: Unyvero LRT/Pneumonia Control Panel M404 is intended for use as an external positive and negative assayed quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of bacterial targets by the Unyvero Lower Respiratory Tract (LRT) Application and Unyvero Hospitalized Pneumonia (HPN) Application performed on the Curetis Unyvero System.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET AND MANUFACTURER NAME AND ADDRESS:

Maine Molecular Quality Controls, Inc (MMQCI) 23 Mill Brook Road Saco, Maine 04072 (USA) E-mail: info@mmqci.com www.mmqci.com Emergency telephone number: 207-885-1072	Manufacturer Phone Number 207-885-1072	Manufacturer Fax Number 207-885-1079
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Section 2 – HAZARD(S) IDENTIFICATION

HAZARDOUS INGREDIENTS:

23% Ethyl Alcohol

Classification: Void

This product is not considered to be flammable under ordinary laboratory conditions based on studies performed by MMQCI.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
					Symbol	R-Phrases
Ethyl Alcohol	200-578-6	603-002-00-5	64-17-5	23	None	None

Dangerous Components According to EC Criteria: None

Section 4 – FIRST AID MEASURES

General: No emergency care is anticipated.

In all cases of doubt or when symptoms occur, do the following:

Inhalation: Remove affected person to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.
Ingestion: Rinse mouth with water. Seek medical attention if signs of toxicity occur.
Skin: Remove contaminated clothing. Wash affected area with plenty of soap and water. Seek medical attention if irritation develops.
Eyes: Rinse immediately with plenty of water. Remove contact lenses if worn. Seek medical attention if redness or irritation develops.

Section 5 – FIRE FIGHTING MEASURES

Flash Point (Method Used): 32°C (90°F) (ethanol vapor), Closed Cup
Flammable Limits: N/A
Extinguishing Media: CO₂ or Dry Chemical / ABC Fire Extinguisher or water
Auto-ignition Temperature: 363°C (ethanol vapor)
Special Fire Hazards: N/A
Explosion Hazards: N/A



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Section 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate protective clothing.
Steps to be Taken in Case Material is Released or Spilled: Wipe up with appropriate absorbent material.
Waste Disposal Method: Normal disposal container

Section 7 – HANDLING AND STORAGE

Handling: Handle per package insert instructions.
Storage: Store at 2-8°C. Do not freeze.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit Values: None
Exposure Controls: This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash station.

PERSONAL PROTECTIVE EQUIPMENT:

Respiratory Protection:	None required	Eye Protection:	Safety glasses
Skin Protection:	Lab coat, gloves	Work / Hygiene Practices:	Standard laboratory precautions
Ventilation:	Normal	Other Protective Equipment:	None required

Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

Component:	Ethanol (23%)	Specific Gravity (H₂O = 1):	N/A
Boiling Point:	86°C (186.8°F)	Evaporation Rate (Butyl Acetate = 1):	N/A
Melting Point:	N/A	Solubility in Water:	Yes
Vapor Density (AIR = 1):	N/A	pH:	N/A
Vapor Pressure (mmHg):	N/A	Odor:	Fruity
Appearance:	Liquid, colorless		

Section 10 – STABILITY AND REACTIVITY

Stability: Stable
Incompatibility (Materials to avoid): None known
Hazardous Decomposition or Byproducts: None known
Conditions to Avoid: Avoid high heat with flames and other sources of ignition.
Hazardous Polymerization: Will not occur

Section 11 – TOXICOLOGICAL INFORMATION

Routes of Entry: N/A
Health Hazards (Acute and Chronic): None known
Carcinogenicity: No
IARC Monographs: N/A
Signs and Symptoms of Exposure: None known
Medical Conditions generally aggravated by Exposure: None known
NTP: N/A
OSHA Regulated: No



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Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity: Regarded as having low toxicity to aquatic organisms.
Mobility: Water soluble, will partition to aqueous phase. Lost within short period through evaporation and dissolution. Poorly absorbed into soils and sediments.
Bioaccumulation: Low bioaccumulation potential.
Degradability: Readily biodegradable.

Section 13 – DISPOSAL CONSIDERATIONS

Appropriate Disposal / Product: Dispose of unused product, spilled substance and waste in normal disposal container.

Section 14 – TRANSPORT INFORMATION

Land Transport: Not restricted. Not regulated as hazardous goods.
Sea Transport: Not restricted. Not regulated as hazardous goods.
Air Transport: Not restricted. Not regulated as hazardous goods.

Section 15 – REGULATORY INFORMATION

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
					Symbol	R-Phrases
Ethyl Alcohol	200-578-6	603-002-00-5	64-17-5	23	None	None

California Proposition 65: This product does not contain any substances listed on California's listing of known or potential carcinogens.
Chemical Safety Assessment: Observe general laboratory safety regulations when handling chemicals.

Section 16 – OTHER INFORMATION

SDS Prepared by: MMQCI
Preparation Date: 31 July 2018

Disclaimer: The information contained in this SDS is provided only for use as a guide. The SDS was carefully prepared based on references and tests believed to be reliable; however, MMQCI makes no guarantee of the accuracy and completeness of the data. Any use of the data must be in accordance with applicable federal, state and local regulations.