



# SAFETY DATA SHEET

REVISION DATE: 3 August 2016

Page 1 of 3

---

## Section 1 – PRODUCT AND COMPANY IDENTIFICATION

---

**PRODUCT NAME:** Xpert<sup>®</sup> CARBA-R QC Panel M215 and Xpert<sup>®</sup> Carba-R QC Panel M219  
**SYNONYMS:** N/A  
**PRODUCT CODES:** M215 and M219

**USE OF THE SUBSTANCE PREPARATION:** The Xpert<sup>®</sup> Carba-R QC Panels are intended for *in vitro* use as a quality control to monitor the detection and identification of multiple pathogens and antibiotic resistance genes associated with Carbapenem-non-susceptibility in gram-negative bacteria obtained from rectal swab specimens from patients at risk for intestinal colonization with Carbapenem-non-susceptible bacteria when tested by the Cepheid Xpert<sup>®</sup> Carba-R Assay on the GeneXpert<sup>®</sup> instrument.

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

<b>Maine Molecular Quality Controls, Inc (MMQCI)</b>	<b>Manufacturer Phone Number</b>	<b>Manufacturer Fax Number</b>
23 Mill Brook Road	207-885-1072	207-885-1079
Saco, Maine 04072 (USA)		
E-mail: <a href="mailto:info@mmqci.com">info@mmqci.com</a>		
<a href="http://www.mmqci.com">www.mmqci.com</a>		
Emergency telephone number: 207-885-1072		

---

## Section 2 – HAZARD(S) IDENTIFICATION

---

**HAZARDOUS INGREDIENTS:** None  
Classification: Void

---

## Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

---

**Chemical Characterization (Hazardous Chemical Ingredients):** 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):** N/A  
**Flammable Limits:** N/A  
**Extinguishing Media:** N/A  
**Auto-ignition Temperature:** N/A  
**Special Fire Hazards:** N/A  
**Explosion Hazards:** N/A



# SAFETY DATA SHEET

REVISION DATE: 3 August 2016

Page 2 of 3

---

## 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:** None

### PERSONAL PROTECTIVE EQUIPMENT:

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

---

## Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

---

<b>Component:</b>	N/A	<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	N/A
<b>Boiling Point:</b>	N/A	<b>Evaporation Rate (Butyl Acetate = 1):</b>	N/A
<b>Melting Point:</b>	N/A	<b>Solubility in Water:</b>	N/A
<b>Vapor Density (AIR = 1):</b>	N/A	<b>pH:</b>	N/A
<b>Vapor Pressure (mmHg):</b>	N/A	<b>Odor:</b>	N/A
<b>Appearance:</b>	N/A		

---

## Section 10 – STABILITY AND REACTIVITY

---

**Stability:** N/A

**Incompatibility (Materials to avoid):** N/A

**Hazardous Decomposition or Byproducts:** N/A

**Conditions to Avoid:** N/A

**Hazardous Polymerization:** N/A

---

## Section 11 – TOXICOLOGICAL INFORMATION

---

**Routes of Entry:** N/A

**Health Hazards (Acute and Chronic):** N/A

**Carcinogenicity:** N/A

**IARC Monographs:** N/A

**Signs and Symptoms of Exposure:** N/A

**Medical Conditions generally aggravated by Exposure:** N/A

**NTP:** N/A

**OSHA Regulated:** N/A



# SAFETY DATA SHEET

REVISION DATE: 3 August 2016

Page 3 of 3

---

## Section 12 – ECOLOGICAL INFORMATION

---

**Ecotoxicity:** N/A  
**Mobility:** N/A  
**Bioaccumulation:** N/A  
**Degradability:** N/A

---

## 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

---

**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: 3 August 2016

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.