



SAFETY DATA SHEET

REVISION DATE: 13 October 2016

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Section 1 – PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Xpert Bladder Cancer Panel C104
SYNONYMS: N/A
PRODUCT CODES: C104

USE OF THE SUBSTANCE PREPARATION: The Xpert Bladder Cancer Panel C104 is intended for *in vitro* use as a quality control to monitor Cepheid Xpert® Bladder Cancer assays on the GeneXpert® System.

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

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

Section 2 – HAZARD(S) IDENTIFICATION

HAZARDOUS INGREDIENTS:

Less than 20% Guanidinium chloride

Classification: Acute Toxicity Oral 4
 Skin Irritation 2
Eye Irritation 2

According to Regulation (EC) No. 1272/2008 (CLP), Globally Harmonized System for Classification and Labeling (GHS), United States Regulations (29 CFR 1910.1200 – Hazard Communication Standard), and Canadian Workplace Hazardous Materials Information System (WHMIS) this material is considered hazardous.

Precautionary Statements

Prevention Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves/protective clothing/eye protection/face protection.

Response If on skin: Wash with plenty of water. Take off contaminated clothing and wash before reuse. Specific treatment, see supplemental first aid information.
If skin irritation occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.
Rinse mouth.
STORAGE/DISPOSAL: Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
					Symbol	Hazard statement code
Guanidinium chloride; guanidine hydrochloride	200-002-3	607-148-00-0	50-01-1	<20		H302 H319 H315



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Section 4 – FIRST AID MEASURES

Inhalation: First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move affected person to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Ingestion: First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Rinse mouth with water and afterwards drink plenty of water. Seek medical attention if signs of toxicity occur.

Skin: First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Wash with plenty of water. Take off contaminated clothing and wash before reuse. If skin irritation occurs: Get medical advice/attention.

Eyes: First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Section 5 – FIRE FIGHTING MEASURES

Flash Point (Method Used): Not flammable

Flammable Limits: N/A

Extinguishing Media: CO₂ or Dry Chemical / ABC Fire Extinguisher or water

Auto-ignition Temperature: N/A

Special Fire Hazards: N/A

Explosion Hazards: N/A

Section 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: Avoid contact with skin and eyes. Wear appropriate personal protective clothing. Ensure adequate ventilation.

Emergency Procedures: No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

Steps to be Taken in Case Material is Released or Spilled: Avoid further leakage or spillage if safe to do so. Wear gloves and wipe up with paper towel.

Waste Disposal Method: Dispose of unused product, spilled substance and waste in accordance with local, regional, national, and/or international regulations.

Section 7 – HANDLING AND STORAGE

Safe Handling: No special handling necessary. Avoid contact with skin and eyes.

Storage: Store at -20°C.

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 and showers.

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

Boiling Point:	Material data lacking	Specific Gravity (H₂O = 1):	N/A
Melting Point:	N/A	Evaporation Rate (Butyl Acetate = 1):	N/A
Vapor Density (AIR = 1):	N/A	Solubility in Water:	Yes
Vapor Pressure (mmHg):	N/A	pH:	5.3 to 5.7
Appearance:	Liquid, colorless	Odor Threshold:	N/A

Section 10 – STABILITY AND REACTIVITY

Stability: Stable



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Incompatibility (Materials to avoid): Strong oxidizing agents
Hazardous Decomposition or Byproducts: Carbon and sodium oxides, hydrogen chloride gas
Conditions to Avoid: Avoid excess heat
Hazardous Polymerization: Will not occur

Section 11 – TOXICOLOGICAL INFORMATION

Routes of Entry: Inhalation, Skin, Eye, Ingestion
Health Hazards (Acute and Chronic): Acute: Harmful if swallowed. Irritating to eye, skin and respiratory system
Chronic: Material data lacking
Carcinogenicity: Material data lacking
IARC Monographs: Material data lacking
Signs and Symptoms of Exposure: Ingestion/Oral exposure: Altered sleep time, excitement, hypermotility, diarrhea
Eye/Skin exposure: irritation
Medical Conditions generally aggravated by Exposure: Material data lacking
NTP: Material data lacking
OSHA Regulated: Yes

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity: Material data lacking.
Mobility: Material data lacking.
Bioaccumulation: Material data lacking.
Degradability: Material data lacking.

Section 13 – DISPOSAL CONSIDERATIONS

Appropriate Disposal / Product: Dispose of unused product, spilled substance and waste in accordance with local, regional, national, and/or international regulations.

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	Hazard statement code
Guanidinium chloride; guanidine hydrochloride	200-002-3	607-148-00-0	50-01-1	<20		H302 H319 H315

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: 13 October 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.