



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 22 April 2024

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## Section 1: IDENTIFICATION OF SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product Identifier

**Tradename:** Xpert SARS-CoV-2 Control Panel M430

**Article number:** M430, M430-OUS

**1.2** Relevant identified uses of the substance or mixture and uses advised against:  
Sector of use SU20 Health services

Application of the substance/the mixture

**1.3** The Xpert SARS-CoV-2 Control Panel M430 is intended for use as reference material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of SARS-CoV-2 by the Xpert® Xpress SARS-CoV-2 *plus* assay performed on the GeneXpert Systems.

### DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET, MANUFACTURER/SUPPLIER:

**Maine Molecular Quality Controls, Inc (MMQCI)**

23 Mill Brook Rd

Saco, Maine 04072 (USA)

E-mail: [info@mmqci.com](mailto:info@mmqci.com)

[www.mmqci.com](http://www.mmqci.com)

**Manufacturer Phone Number**

207-885-1072

**Manufacturer Fax Number**

207-885-1079

**1.4** **Emergency telephone number:** 207-885-1072 (EST 8:30-17:00)

## Section 2: HAZARD(S) IDENTIFICATION

**2.1** **Classification of the substance or mixture:** Not applicable

**Classification according to Regulation (EC) No 1272/2008:** Not applicable

**2.2** **Label elements:**

**Labelling according to Regulation (EC) No 1272/2008:** Not applicable

**Hazard pictograms:** Not applicable

**Signal word:** Not applicable

**Hazard statements:** Not applicable

**2.3** **Other hazards:**

**Results of PBT and vPvB assessment:**

**PBT:** Not applicable

**vPvB:** Not applicable

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

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Chemical Characterization: Mixtures

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	10	None	None

## Section 4: FIRST AID MEASURES

### 4.1 Description of first aid measures:

**General information:** No special measures required.

**After inhalation:** Supply fresh air; consult doctor in case of complaints.

**After skin contact:** Generally, the product does not irritate the skin.

**After eye contact:** Rinse opened eye for several minutes under running water.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

**4.2** **Most important symptoms and effects, both acute and delayed:** Eye irritation

**4.3** **Indication of any immediate medical attention and special treatment needed:** No further relevant information available.

## Section 5: FIRE FIGHTING MEASURES

### 5.1 Extinguishing media:

**Suitable extinguishing media:** Dry powder, Dry sand.

**Unsuitable extinguishing media:** Do NOT use water jet.

**5.2** **Special hazards arising from the substance or mixture:** Carbon oxides

**5.3** **Advice for firefighters:** Wear self-contained breathing apparatus for firefighting if necessary.

**5.4** **Further information:** Use water spray to cool unopened containers.

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## Section 6: ACCIDENTAL RELEASE MEASURES

- 6.1 **Personal Precautions:** Wear appropriate protective clothing.  
 6.2 **Environmental Precautions:** Wipe up with appropriate absorbent material.  
 6.3 **Methods and Material for Containment and Cleaning Up:** Normal disposal container.  
 6.4 **Reference to Other sections:** Section 13 Disposal

## Section 7: HANDLING AND STORAGE

- 7.1 **Precaution for Safe Handling:** Handle per package insert instructions (IFU).  
 7.2 **Conditions for Safe Storage:** Store at -25°C to -15°C.  
 7.3 **Specific End Use(s):** No further relevant information available.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 **Exposure Limit Values:** None  
 8.2 **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:

<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

- 9.1 **Information on basic physical and chemical properties:**  
**Appearance:** Aqueous solution. No data available  
**Odour:** Fruity  
**Odour Threshold:** No data available  
**pH:** No data available  
**Melting point/freezing point:** No data available  
**Initial boiling point and boiling range:** 86°C (186.8°F) (10% ethanol)  
**Flash point:** 44°C (111°F) - closed cup (10% ethanol)  
**Evaporation rate:** No data available  
**Flammability (solid, gas):** No data available  
**Upper/lower flammability or explosive limits:** No data available  
**Vapour pressure:** No data available  
**Vapour density:** No data available  
**Relative density:** No data available  
**Water solubility:** No data available  
**Partition coefficient: n-octanol/water:** No data available  
**Auto-ignition temperature:** No data available  
**Decomposition temperature:** No data available  
**Viscosity:** No data available  
**Explosive properties:** No data available  
**Oxidizing properties:** No data available  
 9.2 **Other information:** No data available

## Section 10: STABILITY AND REACTIVITY

- 10.1 **Reactivity:** No further relevant information available.  
 10.2 **Chemical stability Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.  
 10.3 **Possibility of hazardous reactions:** No dangerous reactions known.  
 10.4 **Conditions to avoid:** No further relevant information available.  
 10.5 **Incompatible materials:** No further relevant information available.  
 10.6 **Hazardous decomposition products:** No dangerous decomposition products known.

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## Section 11: TOXICOLOGICAL INFORMATION

**11.1 Information on toxicological effects:**

Acute toxicity: Based on available data, the classification criteria are not met.

**11.2 Primary irritant effect:**

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

**11.3 CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

## Section 12: ECOLOGICAL INFORMATION

**12.1 Toxicity:**

Aquatic toxicity: Regarded as having low toxicity to aquatic organisms.

**12.2 Persistence and degradability:**

Readily biodegradable.

**12.3 Bioaccumulative potential:**

Low bioaccumulation potential.

**12.4 Mobility in soil:**

Water soluble, will partition to aqueous phase. Lost within short period through evaporation and dissolution. Poorly absorbed into soils and sediments.

**12.5 Results of PBT and vPvB assessment:**

PBT: Not applicable.

vPvB: Not applicable.

**12.6 Other adverse effects:** No further relevant information available.

## Section 13: DISPOSAL CONSIDERATIONS

**13.1 Waste Treatment Methods:**

Dispose of unused product, spilled substance and waste in normal disposal container.

**13.2 Uncleaned packaging:**

**Recommendation:**

Disposal must be made according to official regulations.

**Recommended cleansing agent:**

Water, if necessary, with cleansing agents.

## Section 14: TRANSPORT INFORMATION

**14.1 UN-Number:**

ADR, ADN, IMDG, IATA: Not Regulated

**14.2 UN proper shipping name:**

ADR, ADN, IMDG, IATA: Not Regulated

**14.3 Transport hazard class(es):**

ADR, ADN, IMDG, IATA Class: Not Regulated

**14.4 Packing group:**

ADR, IMDG, IATA: Not Regulated

**14.5 Environmental hazards:**

Marine pollutant: No

**14.6 Special precautions for user:**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:**

Not applicable

## Section 15: REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

**Directive 2012/18/EU:**

**Named dangerous substances - ANNEX I:** None of the ingredients are listed.

**National regulations:**

**Water hazard class:**

Water hazard class 1 (Self-assessment): slightly hazardous for water.

**15.2 Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

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	10	None	None

**California Proposition 65:**  
**Chemical Safety Assessment:**

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



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## Section 16: OTHER INFORMATION

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SDS Prepared by: MMQCI  
Preparation Date: April 2024

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.

### **Abbreviations and acronyms:**

**ADR:** *Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

**IMDG:** *International Maritime Code for Dangerous Goods*

**IATA:** *International Air Transport Association*

**GHS:** *Globally Harmonised System of Classification and Labelling of Chemicals*

**EINECS:** *European Inventory of Existing Commercial Chemical Substances*

**ELINCS:** *European List of Notified Chemical Substances*

**CAS:** *Chemical Abstracts Service (division of the American Chemical Society)*

**PBT:** *Persistent, Bioaccumulative and Toxic*

**vPvB:** *very Persistent and very Bioaccumulative*