



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31  
English

REVISION DATE: 31 October 2022

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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 and 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

- |   |                                    |                |
|---|------------------------------------|----------------|
| <b>14.1 UN-Number:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| <b>14.2 UN proper shipping name:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| <b>14.3 Transport hazard class(es):</b>   | <b>ADR, ADN, IMDG, IATA Class:</b> | Not Regulated  |
| <b>14.4 Packing group:</b>  | <b>ADR, IMDG, IATA:</b>            | Not Regulated  |
| <b>14.5 Environmental hazards:</b>  | <b>Marine pollutant:</b>           | No             |
| <b>14.6 Special precautions for user:</b>                                       |                                    | Not applicable |
| <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:</b> |                                    | 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:** 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.



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## Section 16: OTHER INFORMATION

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SDS Prepared by: MMQCI  
Preparation Date: October 2022

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*