



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 21 August 2024

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

### 1.1 Product Identifier

**Tradename:** Xpert FII & FV NOR/MUT Control

**Article number:** G116, G11601, G11602

**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** Xpert FII & FV NOR/MUT Control is intended for *in vitro* use as a quality control to monitor analytical performance of the Xpert HemosIL<sup>®</sup> Assay on the GeneXpert<sup>®</sup> System. Xpert FII & FV NOR/MUT Control is formulated to monitor the detection of mutations Factor II G20210A and Factor V Leiden G1691A, the most common genetic risk factors for thrombotic events.

### 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	23	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 2°C to 8°C. Do not freeze.  
 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:**
- |  |   |
|--|---|
| <b>Appearance:</b>                                   | Aqueous solution. No data available     |
| <b>Odour:</b>  | Fruity                                  |
| <b>Odour Threshold:</b>                              | No data available                       |
| <b>pH:</b>   | No data available                       |
| <b>Melting point/freezing point:</b>                 | No data available                       |
| <b>Initial boiling point and boiling range:</b>      | 86°C (186.8°F) (23% ethanol)            |
| <b>Flash point:</b>                                  | 44°C (111°F) - closed cup (23% ethanol) |
| <b>Evaporation rate:</b>                             | No data available                       |
| <b>Flammability (solid, gas):</b>                    | No data available                       |
| <b>Upper/lower flammability or explosive limits:</b> | No data available                       |
| <b>Vapour pressure:</b>                              | No data available                       |
| <b>Vapour density:</b>                               | No data available                       |
| <b>Relative density:</b>                             | No data available                       |
| <b>Water solubility:</b>                             | No data available                       |
| <b>Partition coefficient: n-octanol/water:</b>       | No data available                       |
| <b>Auto-ignition temperature:</b>                    | No data available                       |
| <b>Decomposition temperature:</b>                    | No data available                       |
| <b>Viscosity:</b>                                    | No data available                       |
| <b>Explosive properties:</b>                         | No data available                       |
| <b>Oxidizing properties:</b>                         | No data available                       |
| 9.2 <b>Other information:</b>                        | No data available                       |

## Section 10: STABILITY AND REACTIVITY

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

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## Section 16: OTHER INFORMATION

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SDS Prepared by: MMQCI  
Preparation Date: August 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*