



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 25 March 2025

Page 1 of 4

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

### 1.1 Product Identifier

**Tradename:** FilmArray® TF Control Panel M527

**Article number:** M527

**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 FilmArray TF Control Panel M527 is intended for use as an external positive and negative assayed quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of viral, bacterial, and parasitic pathogens on the BIOFIRE® FILMARRAY Tropical Fever Panel performed on the BIOFIRE FILMARRAY 2.0 or TORCH systems.

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

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

**Manufacturer Phone Number**

**Manufacturer Fax Number**

23 Mill Brook Rd

207-885-1072

207-885-1079

Saco, Maine 04072 (USA)

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

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

**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.

# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31  
English

REVISION DATE: 25 March 2025

Page 2 of 4

## 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) (10% ethanol)            |
| <b>Flash point:</b>                                  | 44°C (111°F) - closed cup (10% 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.            |

# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31  
English

REVISION DATE: 25 March 2025

Page 3 of 4

## 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

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



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 25 March 2025

Page 4 of 4

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## Section 16: OTHER INFORMATION

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SDS Prepared by: MMQCI  
Preparation Date: March 2025

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*