



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 01 June 2023

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

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### 1.1 Product Identifier

**Tradename:** INTROL® TB Panel M114, INTROL® TB Panel M114*plus*, MTB/RIF Control Bundle

**Article number:** M114-10, M114-5, M114*plus*, MTB/RIF-BU1

**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** INTROL® TB Panel M114, INTROL® TB Panel M114*plus*, and MTB/RIF Control Bundle are intended for use as quality controls to monitor the performance of *in vitro* laboratory nucleic acid testing procedure for the qualitative detection of *Mycobacterium tuberculosis* (MTB) and multi-drug resistant MTB (MDR-TB) mutations on the GeneXpert® System.

### 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)

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## Section 2: HAZARD(S) IDENTIFICATION

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**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.

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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

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**3.1** **Chemical Characterization:** None

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## Section 4: FIRST AID MEASURES

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### 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.

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## Section 5: FIRE FIGHTING MEASURES

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### 5.1 Extinguishing media:

**Suitable extinguishing media:** Not applicable

**Unsuitable extinguishing media:** Not applicable

**5.2** **Special hazards arising from the substance or mixture:** Not applicable

**5.3** **Advice for firefighters:** Not applicable

**5.4** **Further information:** Not applicable

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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:** None

**PERSONAL PROTECTIVE EQUIPMENT:**

- Respiratory Protection:** None required  
**Skin Protection:** Lab coat, gloves  
**Ventilation:** Normal

- Eye Protection:** Safety glasses  
**Work / Hygiene Practices:** Standard laboratory precautions  
**Other Protective Equipment:** 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:** No data available  
**Flash point:** No data available  
**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.

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: June 2023

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*