



SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 01 December 2022

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

1.1 Product Identifier

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

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

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*, MTB/RIF Control Bundle, and MTB/RIF Ultra 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

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:** 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: 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

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.



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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.

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.



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

Section 16: OTHER INFORMATION

SDS Prepared by: MMQCI
Preparation Date: December 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