



SAFETY DATA SHEET

English

REVISION DATE: 27 August 2024

according to 1907/2006/EC, Article 31

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

1.1 Product Identifier

Tradename: Xpert PML-RARA Control Panel C215, Xpert PML-RARA Linearity Panel C221
Article number: C215, C221

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 PML-RARA Control Panel C215 is intended for use as a reference material to monitor the performance of *in vitro* quantitative detection of PML-RARA transcript isoforms, bcr1, bcr2, bcr3, and ABL1 endogenous control mRNA transcript Cepheid GeneXpert® Instrument Systems. The Xpert PML-RARA Linearity Panel C221 is intended for use as a reference material to monitor the reportable range of *in vitro* laboratory quantitative detection of PML-RARA transcript isoform bcr1 and ABL1 endogenous control mRNA transcript when analyzed using the Xpert® PML-RARA assay on Cepheid GeneXpert® Instrument 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 www.mmqci.com	Manufacturer Phone Number 207-885-1072	Manufacturer Fax Number 207-885-1079
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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:
Classification according to Regulation (EC) No 1272/2008: | Not applicable
Not Applicable |
| 2.2 | Label elements:
Labelling according to Regulation (EC) No 1272/2008:
Hazard pictograms:
Signal word:
Hazard statements: | Not Applicable
Not Applicable
Not Applicable
Not Applicable |
| 2.3 | Other hazards:
Results of PBT and vPvB assessment:
PBT:
vPvB: | Not applicable
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.



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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.

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.
- 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:

- | | | | |
|--------------------------------|------------------|------------------------------------|---------------------------------|
| Respiratory Protection: | None required | Eye Protection: | Safety glasses |
| Skin Protection: | Lab coat, gloves | Work / Hygiene Practices: | Standard laboratory precautions |
| Ventilation: | Normal | 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: | 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 | |



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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.
11.2 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.



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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	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.

Section 16: OTHER INFORMATION

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