



SAFETY DATA SHEET

according to 1907/2006/EC, Article 31
English

REVISION DATE: 24 October 2025

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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 0%, Xpert PML-RARA Linearity Panel C221
Article number: C215, C21612-5, 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 Xpert PML-RARA Control Panel C215, Xpert PML-RARA 0%, and Xpert PML-RARA Linearity Panel C221 are intended for use as assayed external quality controls for the quantitative detection of PML-RARA transcript isoforms and ABL1 endogenous control mRNA transcript when analyzed on Cepheid GeneXpert® 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

1.4 Emergency telephone number: 207-885-1072 (EST 8:00-17:30)

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:
Labeling 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



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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 -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

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
Odor: Fruity
Odor 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
Vapor pressure: No data available
Vapor 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, ADN, 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



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Section 16: OTHER INFORMATION

SDS Prepared by: MMQCI
Preparation Date: October 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:

ADN: *Accord européen relatif au transport international des marchandises Dangereuses par voies de Navigation intérieures (ADN) (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)*

ADR: *Accord européen sur le transport des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

CAS: *Chemical Abstracts Service (division of the American Chemical Society)*

EINECS: *European Inventory of Existing Commercial Chemical Substances*

ELINCS: *European List of Notified Chemical Substances*

GHS: *Globally Harmonised System of Classification and Labelling of Chemicals*

IATA: *International Air Transport Association*

IMDG: *International Maritime Code for Dangerous Goods*

PBT: *Persistent, Bioaccumulative and Toxic*

STOT: *Specific Target Organ Toxicity*

vPvB: *very Persistent and very Bioaccumulative*