



# 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 BCR-ABL1 p190 Control Panel C183, Xpert BCR-ABL1 p190 Linearity Panel C208, Xpert BCR-ABL1 p190 0%  
**Article number:** C17612-5, C183, C208

### 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 BCR-ABL1 p190 0%, Xpert BCR-ABL1 p190 Control Panel C183, and Xpert BCR-ABL1 p190 Linearity Panel C208 are intended for use as assayed external quality controls to monitor the performance of the *in vitro* quantitative detection of p190 BCR-ABL1 translocation mRNA transcript and the 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)**

**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 8:00-17:30)

## 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, 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

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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*