



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: 08 May 2026

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

### 1.1 Product Identifier

**Tradename:** Birlinn® BCR-ABL1 p210 IS Panel C230, Birlinn® BCR-ABL1 p210 IS Control Panel C240  
**Article number:** C230, C230-R, C240, C240-R

### 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 Birlinn BCR-ABL1 p210 IS Panel C230 and Birlinn BCR-ABL1 p210 IS Control Panel C240 are intended to monitor the detection and/or quantification of *BCR-ABL1* (p210) fusion gene using quantitative molecular test 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](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 8:00-17:30)

## 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:** 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

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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:** None
- PERSONAL PROTECTIVE EQUIPMENT:**
- |                                |                  |                                    |                                 |
|--------------------------------|------------------|------------------------------------|---------------------------------|
| <b>Respiratory Protection:</b> | None required    | <b>Eye Protection:</b>             | Safety glasses                  |
| <b>Skin Protection:</b>        | Lab coat, gloves | <b>Work/Hygiene Practices:</b>     | Standard laboratory precautions |
| <b>Ventilation:</b>            | Normal           | <b>Other Protective Equipment:</b> | None required                   |

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 **Information on basic physical and chemical properties:**
- |  |                                     |
|--|-------------------------------------|
| <b>Appearance:</b>                                   | Aqueous solution. No data available |
| <b>Odor:</b>   | Fruity                              |
| <b>Odor threshold:</b>                               | No data available                   |
| <b>pH:</b>   | No data available                   |
| <b>Melting point/freezing point:</b>                 | No data available                   |
| <b>Initial boiling point and boiling range:</b>      | No data available                   |
| <b>Flash point:</b>                                  | No data available                   |
| <b>Evaporation rate:</b>                             | No data available                   |
| <b>Flammability (solid, gas):</b>                    | No data available                   |
| <b>Upper/lower flammability or explosive limits:</b> | No data available                   |
| <b>Vapor pressure:</b>                               | No data available                   |
| <b>Vapor density:</b>                                | No data available                   |
| <b>Relative density:</b>                             | No data available                   |
| <b>Water solubility:</b>                             | No data available                   |
| <b>Partition coefficient: n-octanol/water:</b>       | No data available                   |
| <b>Auto-ignition temperature:</b>                    | No data available                   |
| <b>Decomposition temperature:</b>                    | No data available                   |
| <b>Viscosity:</b>                                    | No data available                   |
| <b>Explosive properties:</b>                         | No data available                   |
| <b>Oxidizing properties:</b>                         | 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

- |   |                                    |                |
|---|------------------------------------|----------------|
| <b>14.1 UN-Number:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| <b>14.2 UN proper shipping name:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| <b>14.3 Transport hazard class(es):</b>   | <b>ADR, ADN, IMDG, IATA Class:</b> | Not Regulated  |
| <b>14.4 Packing group:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| <b>14.5 Environmental hazards:</b>  | <b>Marine pollutant:</b>           | No             |
| <b>14.6 Special precautions for user:</b>                                       |                                    | Not applicable |
| <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:</b> |                                    | 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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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*