



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

English

REVISION DATE: November 06 2024

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

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### 1.1 Product Identifier

**Tradename:** Birlinn™ BCR-ABL1 p210 IS Panel C230, Birlinn™ BCR-ABL1 p210 IS Control Panel C240

**Article number:** C230, C240

**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 8:30-17:00)

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## Section 2: HAZARD(S) IDENTIFICATION

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**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.

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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

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**3.1** **Chemical Characterization:** None

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## Section 4: FIRST AID MEASURES

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**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

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**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

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**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

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## 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:

- 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.  
**Aspiration hazard:** Based on available data, the classification criteria are not met.

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## 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 <b>UN-Number:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| 14.2 <b>UN proper shipping name:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated  |
| 14.3 <b>Transport hazard class(es):</b>   | <b>ADR, ADN, IMDG, IATA Class:</b> | Not Regulated  |
| 14.4 <b>Packing group:</b>  | <b>ADR, IMDG, IATA:</b>            | Not Regulated  |
| 14.5 <b>Environmental hazards:</b>  | <b>Marine pollutant:</b>           | No             |
| 14.6 <b>Special precautions for user:</b>                                       |                                    | Not applicable |
| 14.7 <b>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.

## Section 16: OTHER INFORMATION

SDS Prepared by: MMQCI  
 Preparation Date: November 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