



SAFETY DATA SHEET

according to 1907/2006/EC, Article 31
English

REVISION DATE: 10 March 2026

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

1.1 Product Identifier

Tradename: Birlinn® HH Panel G203
Article number: G203

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 Birlinn HH Panel G203 is intended for *in vitro* use as an external quality control to monitor performance of the detection steps of test systems used in the qualitative measurement of H62D, S65C and C282Y, the mutations most commonly associated with hereditary hemochromatosis.

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 8:00-17:30)

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:**
- | | | | |
|--------------------------------|------------------|------------------------------------|---------------------------------|
| 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 |
| Odor: | Fruity |
| Odor 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 |
| 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
- 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
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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*