

according to 1907/2006/EC, Article 31

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

1.1 Product Identifier

Tradename: Verigene® RP Flex Control Panel M270

Article number: M270

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 Verigene RP Flex Control Panel M270 is intended for *in vitro* use as a quality control to monitor the amplification, detection and identification of multiple viral and bacterial respiratory pathogens as performed by the VERIGENE[®] Respiratory Pathogens *Flex* Nucleic Acid Test (RP *Flex*) on the VERIGENE System.

Manufacturer Phone Number

Manufacturer Fax Number

207-885-1079

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET, MANUFACTURER/SUPPLIER:

207-885-1072

Maine Molecular Quality Controls, Inc (MMQCI)	
23 Mill Brook Rd	
Saco, Maine 04072 (USA)	
E-mail: info@mmqci.com	
www.mmqci.com	
	-

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

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:	
	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 pr	aduation at considered to be flowmable under ordinary laboratory conditions	hand an atudian parformed by MMOCI

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
Chemical Name	EC-NO.	IIIUEX-INU	CA3-NU.		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 su	bstance 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

- **Personal Precautions:** 6.1 Wear appropriate protective clothing.
 - **Environmental Precautions:** Wipe up with appropriate absorbent material.
- 6.2 Methods and Material for Containment and Cleaning Up: Normal disposal container. 6.3
- 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

gloves

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.	
PERSO	VAL PROTECTIVE FOLLIPM	=NT·	

Eye Protection:

Work / Hygiene Practices:

'ERSONAL PROTECTIVE EQUIPMEN

Respiratory Protection:	None required
Skin Protection:	Lab coat, glove
Ventilation:	Normal

Other Protective Equipment:

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1	Information on basic physical and chemical pro	operties:
	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:	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
	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:

- 10.2 Chemical stability Thermal decomposition / conditions to be avoided:
- 10.3 Possibility of hazardous reactions:
- 10.4 Conditions to avoid:
- 10.5 Incompatible materials:
- 10.6 Hazardous decomposition products:

No further relevant information available.

No decomposition if used according to specifications.

Safety glasses

None required

Standard laboratory precautions

- No dangerous reactions known.
- No further relevant information available.
- No further relevant information available.
- No dangerous decomposition products known.

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Section 11: TOXICOLOGICAL INFORMATION

11.1	Information on toxicological effe	ects:
	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 (carcinogenity, mut	agenicity 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 assess	sment:
	PBT: Not applicable.	
	vPvB: Not applicable.	
12.6	Other adverse effects: No furt	her 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 14.2 14.3 14.4 14.5 14.6 14.7	UN-Number: UN proper shipping name: Transport hazard class(es): Packing group: Environmental hazards: Special precautions for user: Transport in bulk according to Annex II of Marpol and the IBC Code:	ADR, ADN, IMDG, IATA: ADR, ADN, IMDG, IATA: ADR, ADN, IMDG, IATA Class: ADR, IMDG, IATA: Marine pollutant: Not applicable Not applicable	Not Regulated Not Regulated Not Regulated Not Regulated No
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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: Chemical Safety Assessment: This product does not contain any substances listed on California's listing of known or potential carcinogens. Observe general laboratory safety regulations when handling chemicals.



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Section 16: OTHER INFORMATION

SDS Prepared by: MMQCI Preparation Date: June 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:

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

International Maritime Code for Dangerous Goods IMDG:

IATA: International Air Transport Association

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