Material Safety Data Sheet

1. Identification of substance

Product name ViraQ run controls

Article numbers and Product Names covered by MSDS

Catalogue number	ViraQ run controls
P0063	P0063 ViraQ HCV Check 125
P0064	P0064 ViraQ HIV-1 Check 125
P0065	P0065 ViraQ HBV Check 125
P0067	P0067 ViraQ HCV Trend 25
P0068	P0068 ViraQ HIV-1 Trend 25
P0069	P0069 ViraQ HBV Trend 25
P0154	P0154 ViraQ HBV Trend 50
P0247	P0247 ViraQ WNV Check 125
P0264	P0264 ViraQ HEV Check 125
P0266	P0266 ViraQ Parvo B19/HAV Check
P0273	P0273 ViraQ Multi-Marker Check 75
P0318	P0318 ViraQ HIV-2 Check 125

Intended Use Performance evaluation (PEO) and, or In vitro diagnostic use only (IVD)

Manufacturer

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Country of origin The Netherlands

In emergencies Call your local emergency centre

2. Hazards identification

Classification according to Regulation (EC) No 1272/2008
The product is not classified according to the CLP regulation

3. Composition and information on ingredients

Potentially biohazardous material: The viral raw materials used for preparation were, when necessary, inactivated by methods which are validated by in vivo experiments and known to reduce infectivity of the agents. Section 13 describes the residual infection risk. The human plasma used for matrix is tested negative for blood borne viruses. However no test method is available which ensures complete absence of (un) known pathological agents

4. First aid measures

Eyes:	In case of contact, immediately rinse eyes with a large amount of water for at least 15 minutes while holding the eyelids open to assure that the entire surface is flushed. Seek medical attention. Risk of transmitting blood borne viruses is limited
Skin:	In case of contact, immediately wash the contact area thoroughly with soap and a large amount of water. Seek medical attention. Risk of transmitting blood borne viruses is limited.
Parental exposure (sharp incident)	In case of parental contact, immediately wash the contact area thoroughly with a large amount of water and cover the wound. Seek medical attention. Risk of transmitting blood borne viruses is limited.
Inhalation	Not applicable
Ingestion:	Avoid swallowing the material. Never give anything by mouth to an unconscious or convulsing person. Seek medical attention. Risk of transmitting blood borne viruses is present.

5. Fire fighting measures

Extinguishing Media:	This product is not combustible. Use any appropriate equipment for the surrounding fire.
Special Fire Fighting Procedures:	Wear self-contained breathing apparatus and full protective clothing to prevent exposure to eyes and skin.
Unusual Fire and Explosion hazards:	May emit toxic vapors under fire conditions.

6. Accidental release measures

Promptly clean up all spills. Wear appropriate personnel protective equipment to avoid exposure. Contain the spill. Absorb the spill using absorbent materials and decontaminate the spill with 10% NaClO solution (bleach) followed by 70% alcohol solution. Dispose of all cleanup materials in accordance with disposal practices for infectious waste as required by (inter)national law. Clean the spill area with water after material pick up is complete.

7. Handling and storage

Handle this material with same precaution as if capable of transmitting infectious agents. Observe routine biosafety precautions in handling. It is strongly recommended to use personal protection which includes, but is not limited to, laboratory coat, gloves and eye safety goggles. Wash thoroughly after handling. Stores run control as labeled.

8. Exposure controls and personal protection

Additional information about design of technical facilities
- No further data; see item 7

Ingredients with limit values that require monitoring at the workplace
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Personal protective equipment

General protective and hygienic measures
- The usual precautionary measures should be adhered to when handling chemicals

Protection of hands
- Protective gloves

Material of gloves
- The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer

Penetration time of glove material
- The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed

Eye protection
- Safety glasses

9. Physical and chemical properties

General information
Appearance

- Form	Solid (stored below<-20°C) Liquid (in usage above >0°C)
Colour	Yellow
Odour	Odourless
- pH value at 20°C	7.0 – 7.4

Change in condition

Melting point/Melting range	Undetermined
Boiling point/Boiling range	Undetermined
- Flash point	Undetermined
- Self-igniting	Product is not self-igniting
- Danger of explosion	Product does not present an explosion hazard
- Density	1.01 g/ml
- Solubility in / Miscibility with water	Fully miscible
- Solvent content:	
Organic solvents	0.0%
Water	>99 %
- Other information	No further relevant information available

10. Stability and reactivity

Stability: This material is stable under ambient temperatures and pressures, is non-corrosive and polymerization will not occur. This material is compatible with other laboratory materials.

Reactivity
Chemical stability

Thermal decomposition/conditions to be avoided
- Do not heat above 37°C

Possibility of hazardous reactions
- No dangerous reactions known when used according to specifications

Conditions to avoid
- No further relevant information available

Incompatible materials
- No further relevant information available

Hazardous decomposition products
- Run control: No dangerous decomposition products known

11. Toxicological information

Potentially bio hazardous material: May be harmful if swallowed, absorbed through skin or parenteral exposure. See section 13 for risk estimation.

12. Ecological information

Toxicity

- Aquatic toxicity	class 1
- Persistence and degradability	No further relevant information available
- Behavior in environmental systems	No further relevant information available
- Bio accumulative potential	No further relevant information available
- Mobility in soil	No further relevant information available

Additional ecological information:

- General notes	Generally not hazardous for water
- Results of PBT and vPvB assessment	Not applicable
- PBT	Not applicable
- vPvB	Not applicable
- Other adverse effects	No further relevant information available

13. Biological safety: risk of virus transmission.

The inactivation methods applied to reduce infectivity of virus in standards from which the run controls were prepared have been validated for plasma products. The table below estimates the risk of virus transmission by accidental parenteral exposure to the product in a worst case setting, i.e. when 0.1 mL of the inactivated virus in the run control would be transfered by sharps.

Table. Infectivity levels expressed in 50% minimum chimpanzee infectious doses (CID_{50}) per mL in product and probability of infection in the unlikely event that 0.1 mL of product would be infused by parenteral exposure

Catalogue number	ViraQ run controls		Inacti-vated	Infectivity level CID_{50} /mL	Probability of infection by transmission by 0.1 mL of product
P0063	P0063 ViraQ HCV Check 125		Yes	<0.004	<0.3%
P0064	P0064 ViraQ HIV-1 Check 125		Yes	<0.0004	<0.003%
P0065	P0065 ViraQ HBV Check 125		Yes	<0.00004	<0.0003%
P0067	P0067 ViraQ HCV Trend 25		Yes	<0.001	<0.05%
P0068	P0068 ViraQ HIV-1 Trend 25		Yes	<0.0001	<0.0005%
P0069	P0069 ViraQ HBV Trend 25		Yes	<0.00001	<0.00005%
P0154	P0154 ViraQ HBV Trend 50		Yes	<0.0002	<0.0001%
P0247	P0247 ViraQ WNV Check 125		No	unknown	Unlikely%
P0264	P0264 ViraQ HEV Check 125		No	<0.001	<0.05%
P0266	P0266 ViraQ Parvo B19/HAV Check	HAV	No	Unknown	
		Parvo B19	No	<0.00001	<1%
P0273	P0273 ViraQ Multi-Marker Check 75		Yes	<0.003	<0.2%
P0318	P0318 ViraQ HIV-2 Check 125		yes	<0.0004#	<0.003%

presumption HIV-2 has similar infectivity as HIV-1

% in vivo and tissue culture experiments show no infectivity after beta-propriolacton treatment

The probability of infection in the table above is based on the remaining infectivity levels in the products and assume rare laboratory incidents (like needle stick or cuts by sharps contaminated with virus). Since there may be unknown infectious agents in the plasma matrix it is recommended to contact a physician for follow-up after such an incident.

14. Transport information

All products are transported on dry ice thereby ensuring products are in solid state. Products are packed in leak-proof bags. The IATA Dangerous Goods Regulations Packaging Instruction 650 is applied.

15. Regulatory information

Labelling according to EU guidelines

- Observe the general safety regulations when handling chemicals.
- The product is not subject to identification regulations under EU Directives

16. Other information

The information provided in this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for specific use of this product. The user is also responsible for observing any laws and applicable guidelines.