1. Identification of substance

1.1 Product identifier list

Article numbers and Product Names covered by MSDS

Catalogue number	Name Nucleic acid panel
P0001	P0001 HBV-DNA genotype A
P0002	P0002 HBV-DNA genotype D
P0004	P0004 HBV-DNA genotype A
P0007	P0007 HBV-DNA genotype A
P0009	P0009 HBV-DNA genotype B
P0010	P0010 HBV-DNA genotype C
P0011	P0011 HBV-DNA genotype D
P0012	P0012 HBV-DNA genotype E
P0013	P0012 HBV-DNA genotype F
P0014	P0014 HBV-DNA genotype G
P0015	P0015 HIV-RNA group O
P0019	P0019 HCV-RNA genotype 1
P0020	P0020 HCV-RNA genotype 3 inact.
P0025	P0025 HIV-1 RNA subtype B
P0026	P0026 HIV-1 RNA subtype B inact.
P0027	P0027 HIV-1 RNA subtype C
P0028	P0028 HIV-1 RNA CRF01_AE
P0030	P0030 HIV-1 RNA subtype B
P0031	P0031 HBV-DNA genotype A inact.
P0032	P0032 HIV-1 RNA subtype A
P0033	P0033 HIV-1 RNA subtype D
P0034	P0034 HIV-2 RNA subtype A
P0035	P0035 HCV-RNA genotype 2
P0036	P0036 HCV-RNA genotype 3
P0037	P0037 HCV-RNA genotype 4
P0038	P0038 HCV-RNA genotype 5
P0039	P0039 HCV-RNA genotype 6
P0041	P0041 HBV-DNA Quant
P0042	P0042 HCV-RNA Quant
P0043	P0043 HIV-1 RNA Quant
P0044	P0044 CMV-DNA Quant
P0045	P0045 HSV-1-DNA Quant
P0046	P0046 HSV-2-DNA Quant
P0047	P0047 parvo B19-DNA Quant
P0051	P0051 HIV-1 RNA CRF02_AG
P0052	P0052 HIV-1 RNA CRF01_AE (2)

Catalogue number	Name Nucleic acid panel
P0053	P0053 HIV-1 RNA subtype F (1)
P0054	P0054 HIV-1 RNA subtype F (2)
P0061	P0061 HCV-RNA genotype 1
P0098	P0098 HIV-1 RNA subtype G (1)
P0099	P0099 HIV-1 RNA M subtype G (2)
P0100	P0100 HIV-1 RNA M subtype H
P0101	P0101 HIV RNA group O (2)
P0102	P0102 HIV-RNA group O (3)
P0103	P0103 HIV-RNA group O (4)
P0104	P0104 HIV-RNA group O (5)
P0106	P0106 WHO HBV-DNA panel genotype A1 (1)
P0107	P0107 WHO HBV-DNA panel genotype A1 (2)
P0108	P0108 WHO HBV-DNA panel genotype A2
P0109	P0109 WHO HBV-DNA panel genotype B1
P0110	P0110 WHO HBV-DNA panel genotype B2
P0111	P0111 WHO HBV-DNA panel genotype B4
P0112	P0112 WHO HBV-DNA panel genotype C (1)
P0113	P0113 WHO HBV-DNA panel genotype C (2)
P0114	P0114 WHO HBV-DNA panel genotype C (3)
P0115	P0115 WHO HBV-DNA panel genotype D (1)
P0116	P0116 WHO HBV-DNA panel genotype D (2)
P0117	P0117 WHO HBV-DNA panel genotype D (3)
P0118	P0118 WHO HBV-DNA panel genotype E
P0119	P0119 WHO HBV-DNA panel genotype F
P0120	P0120 WHO HBV-DNA panel genotype G
P0121	P0121 HBV-DNA panel genotype H
P0122	P0122 HIV-1 RNA subtype B
P0123	P0123 HIV-1 RNA subtype B
P0126	P0126 HCV genotype 4 (2)
P0127	P0127 HCV genotype 5 (2)
P0128	P0128 HCV genotype 6
P0129	P0129 HCV genotype 6n
P0130	P0130 HCV genotype 3b
P0131	P0131 HCV genotype 1a
P0132	P0132 HCV genotype 4a
P0136	P0136 HAV genotype 1a
P0137	P0137 HIV 100 copies/ml subtype ref. panel
P0138	P0138 HBV 100 copies/ml genotype ref. panel
P0139	P0139 HCV 100 copies/ml genotype ref. panel

Catalogue number	Name Nucleic acid panel
P0140	P0140 HIV 1000 copies/ml subtype ref. panel
P0141	P0141 HBV 1000 copies/ml genotype ref. panel
P0142	P0142 HCV 1000 copies/ml genotype ref. panel
P0143	P0143 parvo B19-DNA genotype 1 quant
P0144	P0144 parvo B19-DNA genotype 2 quant
P0153	P0153 HAV genotype reference panel
P0156	P0156 HAV-RNA genotype 1a faeces panel
P0159	P0159 HAV-RNA genotype 1b faeces panel
P0160	P0160 HAV-RNA genotype 1b panel
P0208	P0208 HAV-RNA genotype 2a
P0209	P0209 HAV-RNA genotype 3a
P0261	P0261 HCV-RNA genotype 1
P0262	P0262 HEV-RNA genotype 3
P0274	P0274 HEV-RNA genotype 3a
P0277	P0277 HBV-DNA genotype A
P0278	P0278 HBV-DNA genotype D
P0279	P0279 HBV-DNA genotype A
P0280	P0280 HBV-DNA genotype A
P0281	P0281 HBV-DNA genotype B
P0282	P0282 HBV-DNA genotype C
P0283	P0283 HBV-DNA genotype D
P0284	P0284 HBV-DNA genotype E
P0285	P0285 HBV-DNA genotype F
P0286	P0286 HBV-DNA genotype G
P0287	P0287 HIV-RNA group O
P0288	P0288 HCV-RNA genotype 1
P0289	P0289 HCV-RNA genotype 3 inact.
P0290	P0290 HIV-1 RNA subtype B
P0291	P0291 HIV-1 RNA subtype B inact.
P0292	P0292 HIV-1 RNA subtype C
P0293	P0293 HIV-1 RNA CRF01_AE
P0294	P0294 HIV-1 RNA subtype B
P0295	P0295 HBV-DNA genotype A inact.
P0296	P0296 HIV-1 RNA subtype A
P0297	P0297 HIV-1 RNA subtype D
P0298	P0298 HIV-2-RNA genotype A
P0299	P0299 HCV-RNA genotype 2
P0300	P0300 HCV-RNA genotype 3

Catalogue number	Name Nucleic acid panel
P0301	P0301 HCV-RNA genotype 4
P0302	P0302 HCV-RNA genotype 5
P0303	P0303 HCV-RNA genotype 6
P0304	P0304 HCV-RNA genotype 1
P0319	P0319 HIV-2 RNA subtype A Quant
P0326	P0326 HIV-RNA subtype B panel
P0338	P0338 HIV-2-RNA inact. Panel
P0346	P0346 WNV-RNA lineage 2 inact.
P0350	P0350 HIV-1 RNA subtype B
P0351	P0351 HAV-RNA genotype 1°
P0354	P0354 HIV-2 RNA subtype A (WHO 16/296)
P0356	P0356 SARS-CoV-2 stand. dil panel
P0359	P0359 SARS-2 stand. dil panel SARS-Ag
P0360	P0360 WNV-RNA lineage 1
P0387	P0387 WHO SARS-CoV-2 stand. dil panel

1.2 Relevant identified uses of the substance or mixture and uses advised against

Intended Use Research use only (RUO) or Original Equipment Manufacturer OEM, see also inserts implied products

1.3 Details of the supplier of the safety data sheet

Biologicals Quality Control BV
Droogmakerij 31h
1851 LX Heiloo, The Netherlands

Tel: +31 (0)72-2020 730 (business hours)
Fax: +31 (0)72-2020 731
e-mail: info@bioqcontrol.com
Web: www.bioqcontrol.com
Country of origin The Netherlands

1.4 Emergency telephone number

GSM: +31 (0)6-143 57 205 or 31 (0) 6 252 33 379 (24 hours a day)

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

This product is not classified as hazardous according to the Regulation (EC) No 1272/2008 and subsequent amendments.

This product is not classified as hazardous according to the Globally Harmonized System (GHS)

This product is not classified as hazardous according to OSHA GHS regulations within the U.S.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

This product does not have a classification according to the CLP regulation.

This product is not classified as hazardous according to the OSHA GHS regulations within the U.S.

GHS Elements	Not Regulated
Hazard Pictograms	Not Regulated
Signal Word	Not Regulated
Hazard-determining components of labelling	None
Hazard statements	Not Regulated

2.3 Other hazards

Not Otherwise Classified (HNOC) or covered by GHS

The listed standard dilutions of Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis E, Parvo B19 and Human immunodeficiency virus are BIOHAZARDOUS material containing ACTIVE VIRUS and should be handled in accordance with EU Directives 2000/54/EC1112 on the protection of workers from risks related to exposure to biological agents at work / in accordance with biosafety guidelines defined in the BMBL, NIH-CDC HHS publication No. (CDC) 21-

Category: WHO risk group 3

Emergency Overview: Biohazardous

Pathogenicity: Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis E, Parvo B19 and Human immunodeficiency virus cause infection in humans, hepatitis E virus is a zoonotic viruses.

Host Range: Humans, hepatitis E virus also pigs.

Risk estimation of biohazards; capability to transmit infections.

All data were obtained from in vivo experiments and indicate the biological safety levels. We emphasize risks may differ for individuals.

The products may impose a risk on transmission of infection with Hepatitis A virus (HAV), Hepatitis B virus (HBV), Hepatitis C virus (HCV). Hepatitis E virus (HEV), Human Immunodeficiency virus type 1 or type 2 (HIV), parvo B19 virus (parvo), the name of the product mention the virus present.

Virus	Transmission routes by product	Infectious dose in copies (ID_{50})	Reduction ID_{50} by inactivation method	Antibodies present in matrix	Vaccination possible
HAV	Needle stick incidents	(10-100)	Not applicable	Yes	Yes
HBV	Needle stick incidents	1-10	10^6	No	Yes
HCV	Needle stick incidents	1-10	$<10^2$	No	No
HEV	Needle stick incidents	~1000	Not applicable	Yes	No
HIV-1,-2	Needle stick incidents	1-10	$>10^4$	No	No
Parvo	Needle stick incidents	~10.000	Not applicable	Yes	No
WNV	Needle stick incidents	1-10	Not applicable	No	No
COVID-19	Air	unknown	Not applicable	yes	Yes

The ID_{50} levels indicate common laboratory incidents like needle stick or cuts by sharps are events where transmission of infection may occur. In all cases please contact immediately a physician for treatment and/or post-exposure prophylaxis after the incident. Use the MSDS, product inserts; reported sample concentration and estimations about the transmitted volume for risk estimation. We recommend vaccination when available to reduce risk, prevent on transmission.

Results of PBT and vPvB assessment

PBT Not applicable

vPvB Not applicable

3. Composition and information on ingredients

Biohazardous material: The viral raw materials used for preparation are not treated to reduce their infectivity. When "inactivated" is mentioned in the name, infectivity reduction is done, and depending on the agent residual infectivity may still be present.

The matrix applied for dilution is prepared from recovered negative human plasma units released for use in human or manufacturing of plasma products. The units were pooled (n~100) and spiked with Ethylenediamineacetic acid (CAS: 60-00-4, EC NO: 200-449-4) to a final concentration of 5mM.

4. First aid measures

4.1 Description of 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 present

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 present.

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.

4.2 Most important symptoms and effects, both acute and delayed

Not available

4.3 Advice for fire fighters

Protective equipment, no special measures required.

5. Firefighting 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

6.1 Personal precautions, protective equipment and emergency procedures

To minimize contact, wear a laboratory coat, nitrile or latex gloves, and protective glasses.

6.2 Environmental precautions

Dispose as infectious material.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material. Disinfect area with 10% NaClO solution (bleach) followed by 70% alcohol solution.

6.4 Reference to other sections

See Section 7 for Safe Handling. See Section 8 for Exposure Controls. See Section 13 for Disposal

7. Handling and storage

7.1 Precautions for safe handling

Handle this material with precautions for infectious agents; blood borne viruses. Observe routine biosafety precautions (biosafety level 2: BSL-2) in handling. You must use personal protection which includes, but is not limited to, laboratory coat, gloves and eye safety goggles. Wash thoroughly after handling. Wear appropriate protective equipment (see Section 8). Practice good work hygiene.

7.2 Conditions for safe storage, including any incompatibilities

Store product control as labeled.

7.3 Specific end use(s)

No further relevant information available

8. Exposure controls and personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace: not present.

8.2 Exposure controls

Personal protective equipment

General protective/hygienic measures	The usual precautionary measures are to be adhered to when handling chemicals and biological material.
Ventilation	Work in a biological safety cabinet to reduce the possibility of exposure.
Respiratory protection	Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard, if a risk assessment indicates this is necessary.
Protection of hands	Protective gloves (i.e. nitrile or equivalent).
Eye protection	Safety glasses or safety goggles, as appropriate.
Body protection	Protective work clothing and laboratory coats.

9. Physical and chemical properties

9.1 General information

Appearance

Form	Solid (stored below<-30/70°C)
	Liquid (in usage above >0°C)
Color	Yellow
Odor	Odorless
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 %

9.2 Other information

No further relevant information available

10. Stability and reactivity

10.1 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.

10.2 Chemical stability

No further relevant information available

Thermal decomposition/conditions to be avoided; do not heat above 37°C

10.3 Possibility of hazardous reactions

No dangerous reactions known when used according to specifications

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

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met.
LD_{50}/LC_{50} values relevant for classification	Unknown
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.
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.

12. Ecological information

12.1 Toxicity

Aquatic toxicity	No further relevant information available
12.2 Persistence and degradability	No further relevant information available
12.3 Bio accumulative potential	No further relevant information available
12.4 Mobility in soil	No further relevant information available
General notes	Avoid release to the environment

12.5 Results of PBT and vPvB assessment

PBT	None of the substances present are considered PBT
vPvB	None of the substances present are considered vPvB
12.6 Other adverse effects	No further relevant information available

13. Disposal considerations

13.1 Waste treatment methods

Recommendation	The user of this product has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state, and federal laws and regulations regarding treatment, storage, and disposal for hazardous and nonhazardous wastes.
Uncleaned packaging recommendation	Disposal must be made according to official regulations
Recommended cleansing agents	Disinfection with 10% sodium hypochlorite (bleach).

14. Transport information

14.1 UN Number

DOT, ADR, IMDG, IATA	UN3373

14.2 UN proper shipping name

DOT, ADR, IMDG, IATA	"Biological Substance, Category B"

14.3 Transport hazard class

DOT, ADR, IMDG, IATA	Class 6, division 6.2

14.4 Packing group

DOT, ADR, IMDG, IATA	Guidance in PI650, IATA
14.5 Environmental hazards	Mixture Not Classified Marine Pollutant
Marine Pollutant	Mixture not classified marine Pollutant
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

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Unites States (USA)

SARA Section 355	None of the ingredients are listed.
SARA Section 302/304/311/312/313	None of the ingredients are listed.
TSCA (Toxic Substances Control Act)	All chemicals are listed.
Proposition 65 (California)	None of the ingredients are listed.
Chemicals known to cause Cancer	None of the ingredients are listed.
Chemicals known to cause reproductive toxicity for females	None of the ingredients are listed.
Chemicals known to cause developmental toxicity	None of the ingredients are listed.
Carcinogenic Categories	
EPA (Environmental Protection Agency)	None of the ingredients are listed.
IARC (International Agency for Research on Cancer)	None of the ingredients are listed.
NIOSH-Ca	None of the ingredients are listed.

Canada

Canadian Domestic Substances List (DSL)	None of the ingredients are listed.
International Regulations	WHO/HSE/GCR/2015.2: UN3373
Other regulations, limitations and prohibitive regulations	
Seveso III Directive (2012/18/EU)	None of the ingredients are listed.
Substances of very high concern (SVHC)	None of the ingredients are listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information

Disclaimer The above information is believed to be accurate but does not purport to be all inclusive and shall be used only as a guide. Biological Quality Control B.V (BioQControl) shall not assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DOT: US Department of Transportation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC50/LD50: Lethal concentration, 50 percent/Lethal dose, 50 percent

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety and Health Administration

PBT/vPvB: Persistent, Bio accumulative and Toxic/very Persistent and very Bio accumulative

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)

SARA: Superfund Amendments and Reauthorization Act

STEL: Short Term Exposure Limit

STOT: Specific Target Organ Toxicity

SVHC: Candidate List of Substances of Very High Concern

TWA: Time Weighted Average

Date of Preparation

The effective date in the header of this document is the date of preparation and/or last revision