

SAFETY DATA SHEET PCR Kit

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Synonyms, commercial names – Not available
Product name: GeneProof Hepatitis B Virus (HBV) PCR Kit

Brand: GeneProof a.s.
Index No: Not applicable
REACH No: Not applicable
CAS No: Not applicable

In accordance with the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, this CE IVD product does not comply with requirements for obligation of making safety data sheet.

This product is in accordance with requirements of European parliament and Council directive 98/79/EC for *in vitro* diagnostics.

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

Detection of DNA/RNA sequences specific for selected pathogens, which is used for diagnostics purposes in healthcare.

1.3 Details of the supplier of the safety data sheet

Manufacturer: GeneProof a.s.
Videňská 101/119
Dolní Heršpice, 619 00 Brno
Česká republika (CZ)
Tel.: +420 543 211 679
Fax: +420 516 770 824
www.geneproof.com | info@geneproof.com

1.4 Emergency telephone number

Toxicological information centre of Czech Republic +420224919293
Toxicological information centre outside of Czech Republic: <https://echa.europa.eu/support/helpdesks>

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not hazardous to health. Not considered flammable or environmental hazard according to current laws.

2.2 Label elements

Not applicable to the products.

2.3 Other hazards

Not applicable to the products.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable to the products.

3.2 Mixtures

MasterMix (Nucleotidyl transferase mix 4 - 65 %, water 10 - 35 %, oligonucleotides ± 2 %, DMSO ± 6 %, Magnesium chloride ± 15 %, Uracil-DNA Glycosylase < 1 %).
Substances and mixtures are not dangerous according to the Directive (EC) no. 1272/2008.

Positive control/Calibrators (nucleic acid ± 10 %, Tris-EDTA buffer ± 90 %).
Substances and mixtures are not dangerous according to the Directive (EC) no. 1272/2008.

Internal Standard (nucleic acid ± 10 %, Tris-EDTA buffer ± 90 %).
Substances and mixtures are not dangerous according to the Directive (EC) no. 1272/2008.
Other information: data not available.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

General notes

It is recommended that the PCR products are handled by demonstrably trained laboratory staff with particular respect to molecular techniques and handling with potentially infectious biological materials. Do not drink, eat and smoke during the laboratory work.

Aspiration

No hazardous at aspiration.

Skin contact

No hazardous in contact.

Contact with eyes

Remove contact lens. After contact with the eyes rinse thoroughly under running water with the eyelid wide open with eye washing bottle, eye douche or running water at least for 15 minutes (protect intact eye). If necessary, call a doctor.

Swallowing

Rinse you mouth thoroughly with water.

First aider protection

Not necessary.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Not demanded.

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Appropriate extinguishing: water spray or fog.

5.2 Special hazards arising from the substance or mixture

No special hazard.

5.3 Advice for firefighters

There is no particular danger in the fire. Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Other information

No information available.

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SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Not applicable to the products.

6.2 Environmental precautions

Not applicable to the products.

6.3 Methods and materials for containment and cleaning up

Wipe with a moist piece of cloth and place it into a container. Cover the container and remove it. Wash the area with water.

6.4 Reference to other sections

See section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not breathe the vapours/dust. Avoid contact with skin, eyes and ingestion. In areas of use and storage, it is necessary to avoid smoking, drinking and eating. For personal protection, see section 8.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature: see label.

Keep tubes tightly closed. Open tubes must be carefully resealed and kept upright to prevent leakage. Observe label and package insert precautions. Store at locations secured from children, do not place into food, feed, medicine, etc. containers and packages.

7.3 Specific end use

Laboratory chemical.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Data not available.

8.2. Exposure control

Product does not contain any amount of critical substances which have to be controlled.

Personal exposure control

Eye/face protection

Not required.

Hand protection

Gloves according EN 374 (permeation time >30 min - level 2), consist of PVC, natural latex, Neoprene, or Nitrile (for example: Ansell or KCL).

Respiratory protection

Not required.

Skin and body protection

Wear appropriate laboratory clothes (e.g. smock).

Personal hygiene

Eating, drinking, smoking, taking snuff and storage of food in work areas and at outdoor workplaces is prohibited. Avoid contact with the skin, eyes and clothing. Wash hands thoroughly with soap and water when stopping work and before eating, and then apply protective skin cream.

Environmental exposure controls

Do not let product enter drains.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

MasterMix

Appearance: Liquid

Color: Light pink

Odor: Odorless

pH: 6,8 – 7,2

Positive control/Calibrator

Appearance: liquid

Color: Colourless

Odor: Odorless

pH: 6,8 – 7,2

Internal Standard

Appearance: Liquid

Color: Colourless

Odor: Odorless

pH optimum: 6,8 – 7,2

Unlisted physicochemical properties (specific gravity, melting point, vapour pressure, solubility in water, partition coefficient, effervescence and oxidising properties, odour threshold, melting point/freezing point, initial boiling point and boiling range, evaporation rate, flammability (solid/gas), upper/lower flammability or explosive limits, vapour pressure, vapour density, relative density, solubility, partition coefficient, auto-ignition temperature, decomposition temperature, viscosity, explosive properties, oxidising properties) not available.

9.2 Other information

Not applicable to the products.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

Mixture is stable and unreactive.

10.2 Chemical stability

Not applicable to the products.

10.3 Possibility of hazardous reactions

Not applicable to the products.

10.4 Conditions to avoid

Not applicable to the products.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Not applicable to the products.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

No components (MasterMix, Positive control/Calibrators, Internal standard) of *in vitro* medical device are consider as toxic, no declaration necessary.

Germ cell mutagenicity, carcinogenicity, reproductive toxicity, toxicity for specific body organ – one time exposition, toxicity for specific body organ – repeated exposition: Not applicable for the products.

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SECTION 12. ECOLOGICAL INFORMATION

No components of *in vitro* medical device are considered as toxic.

12.1 Toxicity
Not applicable to the products.

12.2 Persistence and degradability
Not applicable to the products.

12.3 Bio accumulative potential
Not applicable to the products.

12.4 Mobility in soil
Not applicable to the products.

12.5 Results of PBT and vPvB assessment
Not applicable to the products.

12.6 Other adverse effects
Not applicable to the products.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Paper and plastic part of the package placed in separate waste.

SECTION 14. TRANSPORT INFORMATION
Safety special conditions for transport are not required. Transport in a box should be at temperature below - 20 °C for quality maintaining.

14.1 UN Number
Not required.

14.2 UN proper shipping name
Not required.

14.3 Transport hazard class
Not required.

14.4 Packing group
Not required.

14.5 Environmental hazard
See section 6 and 11

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

In accordance with the Regulation of the European Parliament and Council Regulation (EC) no. 1907/2006 on the registration, evaluation, authorization and restriction of chemicals, establishing a European Chemicals Agency, amending Directive 1999/45 / EC and repealing Council Regulation (EEC) no. 793/93 and Commission Regulation (EC) no. 1488/94, Council Directive 76/769 / EEC and Commission Directives 91/155 / EEC, 93/67 / EEC, 93/105 / EC and 2000/21 / EC. This CE IVD product does not comply with requirements for obligation of making safety data sheet.

This product does not comply with the Regulation of the European Parliament and Council Regulation (EC) no. 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) no. 1907/2006, article 1, paragraph 5

This product is for *in vitro* diagnostics in accordance with requirements of European parliament and Council directive 98/79/EC.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Not applicable to the product.

15.2 Chemical safety assessment
Not applicable to the product.

SECTION 16. OTHER INFORMATION

16.1 H-phrases (in accordance with 1272/2008)
Not applicable to the products.

16.2 P-phrases (Precautionary statements based on 1272/2008)
Not applicable to the products.

16.3 Training Advice
The staff must be trained and the training must be verifiably.

16.4 History of document changes
Change list of the document is available on request by GeneProof, a.s.
Revision: DOK_430_18_03: Address update. Sections 1.2, 5.3 and 10.5 update. Overall grammar and linguistic corrections.

16.5 General
GeneProof a.s. provides the information contained herein in good faith being up-to-date of own realizations at revision time.
This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product.
Individuals receiving the information must exercise their independent judgement in determining its appropriateness for a particular purpose.

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If you have any questions, please contact our Customer Service.

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