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 Borrelia burgdorferi PCR Kit

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

In accordance with the Regulation of the European Parliament and Council Regulation (EC) no. 1907/2006 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 products.

1.2 Relevant identified uses of the substance or mixture and uses advised against
Set is designed for fungal DNA extraction from many types of clinical materials.

1.3 Details of the supplier of the safety data sheet
Manufacturer: GeneProof a.s.
Vídeňská 119, 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. HAZARD 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/Calibrator (nucelic acid ± 10 %, Tris-EDTA buffer= 90 %).
Substances and mixtures are not dangerous according to the Directive (EC) no. 1272/2008.

Internal Standard (nucelic 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 handlig with potencionally infectious biological materials. Don´t 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
Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Other information
No information available.

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 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. Tubes which are opened 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	Positive control/Calibrator	Internal Standard
Appearance: Liquid	Appearance: liquid	Appearance: Liquid
Color: Light pink	Color: Colourless	Color: Colourless
Odor: Odorless	Odor: Odorless	Odor: Odorless
pH: 6,8 – 7,2	pH: 6,8 – 7,2	pH optimum: 6,8 – 7,2

Unlisted physico-chemical 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
Not applicable to the products.

10.6 Hazardous decomposition products
Not applicable to the products.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
All components (MasterMix, Positive control/Calibrator, Internal standard) of medical device *in vitro* are not 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

All components of medical device *in vitro* are not considered 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_17_02: Attachment is divided to two separate parts Czech form and English form.

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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