According to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/833/EU.



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

Product identifier 1.1

		REF	Product name				
COV2A/GP/025 COV2A/GP/100		GeneProof SARS-CoV-2 Advanced PCR Kit					
#		Name		Volume	COV2A/GP/025	COV2A/GP/100	
1		MasterMix		375 µl	1	4	
2		Positive Control		200 µl	1	2	

Index No: Not applicable REACH No: Not applicable CAS No: Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against Detection of RNA sequence specific for selected pathogen

Details of the supplier of the safety data sheet 1.3

Manufacturer: GeneProof a.s. Vídeňská 101/119 Dolní Heršpice, 619 00 Brno Czech Republic Tel.: +420 730 176 222 www.geneproof.com | info@geneproof.com

E-mail to the Competent person responsible for the safety data sheet: support@geneproof.com 1.4 Emergency telephone number <u>Czech Republic:</u> Toxikologické informační středisko Na Boiišti 1 120 00 Praha 2 Tel.: +420 224 919 293, +420 224 915 402

<u>Slovakia:</u> Národné toxikologické informačné centrum Limbová 5 833 05 Bratislava Tel.: +421 2 54 77 41 66

Other countries:

Poison Centers and Clinical Toxicologists all over the World https://www.eapcct.org/index.php?page=links

Section 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture 2.1

All mixtures of the product do not meet the criteria for classification in accordance with Regulation (EC) No. 1272/2008 (CLP).

2.2 Label elements

All mixtures of the product do not meet the criteria for labeling in accordance with Regulation (EC) No. 1272/2008 (CLP).

Other hazards 2.3

Listed substances/mixtures does not meet the PBT and vPvB criteria. No additional data available. vPvB: Not applicable

Section 3 COMPOSITION/INFORMATION ON INGREDIENTS

Substances 3.1 Not applicable.

3.2 Mixtures Not applicable.

Section 4 FIRST AID MEASURES

4.1 Description of first aid measures

General notes The PCR kit is only for professional use. 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. Supply fresh air or oxygen. Respiratory problems: consult a doctor/medical service.

Following skin contact Not hazardous in contact.

Following eye contact

Rinse immediately with plenty of water for 15 minutes. Remove contact lenses carefully if present. Continue rinsing. Do not apply neutralizing agents. Following swallowing Rinse you mouth thoroughly with water.

First aider protection Not necessary

4.2

Most important symptoms and effects, both acute and delayed No data available.

Following eye contact: No data available Following skin contact: No data available.

4.3 Indication of any immediate medical attention and special treatment needed Specific treatment not determined. Treat symptomatically.

Section 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Water spray or fog, alcohol resistant foam, dry extinguishing powder, carbon dioxide (CO₂). Unsuitable extinguishing media No information available.

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Special hazards arising from the substance or mixture 5.2 No information available

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

Section 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures 6.1 Not applicable to the products

Environmental precautions

6.2 Environmental pre Not applicable to the products

6.3 Methods and material for containment and cleaning up Not applicable to the products

Reference to other sections 6.4

See section 7 for information on safe handling. See section 8 for information on personal equipment.

See section 13 for disposal information.

Section 7 HANDLING AND STORAGE

Precautions for safe handling 7.1

Ensure good ventilation/exhaustion at the workplace. Prevent formation of dust. Any unavoidable deposit of dust must be regularly removed. Keep away from naked flames/heat. Clean contaminated clothing. Keep container tightly closed. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature: see label. Store in a dry place. Keep container tightly closed. Store in a well-ventilated place. Protect from sunlight. Open tubes must be carefully resealed and kept upright to prevent content spilling.

Specific end use(s) 7.3 No information available

Section 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control parameters**

No data available

8.2. Exposure control No data available

General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Vacuum clean contaminated clothing. Do not blow or brush off contamination. Avoid contact with the eyes and skin.

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

Eve/face protection Not required.

Hand protection Wear suitable gloves, which are tested according to EN 374. type of material consists of PVC, natural latex, Neoprene, or Nitrile espiratory protection Not required.

Environmental exposure controls Keep away from drains, surface and ground water.

Section 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

9.1 Information on basic physical and chemical properties					
Substance/Mixture	MasterMix	Positive Control			
Physical state	Liquid	Liquid			
Colour	Light pink	Colourless			
Odour	Odourless	Odourless			
рН	No data available	No data available			
Melting point/freezing point	No data available	No data available			
Boiling point or initial boiling point and boiling range	No data available	No data available			
Flash point	No data available	No data available			
Evaporation rate	No data available	No data available			
Flammability (solid, gaseous)	No data available	No data available			
Lower and upper explosion limit	No data available	No data available			
Vapour pressure (20 °C)	No data available	No data available			
Vapour pressure (50 °C)	No data available	No data available			
Relative vapour density	No data available	No data available			
Density and/or relative density	Undetermined	Undetermined			
Solubility (20 °C)	Water	Water			
Partition coefficient n- octanol/water (log value)	No data available	No data available			
Autoignition temperature	No data available	No data available			
Decomposition temperature	No data available	No data available			





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Kinematic viscosity	No data available	No data available
Refractive index (20 °C)	No data available	No data available
Oxidizing properties	No data available	No data available
Explosive properties	No data available	No data available
Particle characteristics	No data available	No data available

9.2 Other information No information available

STABILITY AND REACTIVITY

10.1 Reactivity No information available

Section 10

10.2 Chemical stability

No information available

10.3 Possibility of hazardous reactions No information available

10.4 Conditions to avoid No information available

10.5 Incompatible materials

No information available

10.6 Hazardous decomposition products No information available

Section 11

on 11 TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 No mixtures of the product are considered to be toxic, no declaration necessary.

Exposition	MasterMix	Positive Control	
Skin corrosion/irritation	Based on available data, the classification criteria are not met		
Serious eye damage/eye 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		
Summary of evaluation of the CMR properties	Based on available data, the classification criteria are not met		
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met		
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met		
Aspiration hazard	Based on available data, the classification criteria are not met		

11.2 Information on other hazards

No data available. Section 12

Section 12 ECOLOGICAL INFORMATION 12.1 Toxicity No data available.

12.2 Persistence and degradability

No data available. 12.3 Bio accumulative potential

No data available.

12.4 Mobility in soil No data available.

12.5 Results of PBT and vPvB assessment No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects No data available.

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 or ID number

Not required. 14.2 UN proper shipping name

Not required.

14.3 Transport hazard class(es) Not required.

14.4 Packing group Not required.

14.5 Environmental hazards

Not required. 14.6 Special precautions for

 14.6
 Special precautions for user

 See section 6 and 11

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14.7 Maritime transport in bulk according to IMO instruments

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 (EC) 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.

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

15.2 Chemical safety assessment

Not applicable.

Section 16 OTHER INFORMATION

16.1 H-phrases (in accordance with 1272/2008)

Not applicable.

16.2 P-phrases (Precautionary statements based on 1272/2008)

Not applicable.

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

16.4 History of document changes

Change list of the document is available on request by GeneProof, a.s.

Revision: SDS_0037_A01_1.0 New document. 16.5 Abbreviations and acronyms

 16.5
 Abbreviations and acronyms

 PBT
 persistent, bioaccumulative and toxic

vPvB very persistent and very bioaccumulative

16.6 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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