

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), amended by Regulation (EU) 2020/878.

Creation/Revision date: 13. 4. 2022
Version: SDS_0089_A02_1.0

GeneProof[®]
Molecular diagnostics for your routine

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

1.1 Product identifier

Product	Package	REF
GeneProof Mycobacterium tuberculosis PCR Kit	25 reactions	MT/ISEX/025
GeneProof Mycobacterium tuberculosis PCR Kit	100 reactions	MT/ISEX/100

Kit content

Cap Colour	Vial Title	Volume [µl]	Quantity	
			MT/ISEX/025 - for 25rxn	MT/ISEX/100 - for 100rxn
Blue	MasterMix <i>Mycobacterium tuberculosis</i>	750	1	4
White	Positive Control <i>Mycobacterium tuberculosis</i>	200	1	2
Red	Internal Standard <i>Bordetella</i> <i>Chlamydia pneumoniae</i> <i>Mycobacterium tuberculosis</i> <i>Mycoplasma pneumoniae</i>	1000	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

The kit has been manufactured as an in vitro diagnostic medical device and it has been designed for professional use in specialized clinical and research laboratories.

1.3 Details of the supplier of the safety data sheet

Manufacturer:
GeneProof a.s.
Václavská 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

Czech Republic:
Toxikologické informační středisko
Na Bojišti 1
120 00 Praha 2
Tel.: +420 224 919 293, +420 224 915 402

Slovakia:
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

2.1 Substance or mixture classification

All mixtures of the product are not classified as dangerous according to Regulation (EC) No. 1272/2008 (CLP).

2.2 Label elements

Labeling according to Regulation (EC) No. 1272/2008 (CLP) is not required.

2.3 Other hazards

All mixtures of the product do not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH).

Section 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Mixtures do not contain hazardous substances and substances with the highest permissible concentration in the working environment.

Section 4 FIRST AID MEASURES

4.1 Description of first aid measures

Following inhalation

Terminate the exposure immediately, remove the affected person to fresh air.

Following skin contact

Rinse the affected area with running water. Take off contaminated clothing.

Following eye contact

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Following swallowing

Rinse out your mouth with clean water. Get medical attention if you feel unwell.

First aider protection

Not necessary

4.2 Most important symptoms and effects, both acute and delayed

Not expected.

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

Choose extinguishing media according to the surroundings of the fire.

Unsuitable extinguishing media

No information available.

5.2 Special hazards arising from the substance or mixture

No information available.

5.3 Advice for firefighters

It is advisable to use a self-contained breathing apparatus, chemical resistant gloves and a full-body protective clothing.

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Section 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Follow the principles of work safety in the laboratory.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Store material as instructed in the Section 7. In the event of a leak, remove the material with a cloth and wash the contaminated area with plenty of water.

6.4 Reference to other sections

See the section 7 for information on safe handling.
See the section 8 for information on personal equipment.
See the section 13 for disposal information.

Section 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Follow good laboratory practice.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature: see label.

Keep only in the original container. Store in a dry place. Keep container tightly closed. Protect from sunlight. Open tubes must be carefully resealed and kept upright to prevent content spilling.

7.3 Specific end use(s)

No information available.

Section 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Mixtures of the product do not contain substances for which occupational exposure limits are set.

8.2 Exposure controls

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. Avoid contact with the eyes and skin.

Eye/face protection

Not required.

Skin protection

Wear suitable gloves, which are tested according to EN 374.
type of material consists of PVC, natural latex, Neoprene, or Nitrile

Respiratory 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

Substance/Mixture	MasterMix	Positive Control	Internal Standard
Physical state	Liquid at 20°C	Liquid at 20°C	Liquid at 20°C
Colour	Light pink	Colourless	Colourless
Odour	Odourless	Odourless	Odourless

9.2 Other information

No information available

Section 10 STABILITY AND REACTIVITY

10.1 Reactivity

No information available

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 TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the mixture.
Based on available data the classification criteria are not met.

11.2 Information on other hazards

No endocrine disrupting properties are known.

Section 12 ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Product mixtures do not contain substances meeting the criteria for PBT or vPvB substances in accordance with Annex XIII, Regulation (EC) No. 1907/2006 (REACH).

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

Recommended disposal method for legal persons and physical persons authorised to enterprise:
Must not be disposed of together with municipal waste. No to be discharged to the sewerage. Avoid release to the environment. Place unused preparation and contaminated packaging into labelled waste collection containers, hand over labelled waste for disposal to a specialised company authorised to carry out such activities.
Recommended disposal method: the product shall be recycled, if possible, or incinerated in an approved plant. Incineration or landfilling may be considered only when recycling is not possible. Contaminated packaging must be cleaned before being recycled. Cleaned packaging shall be recycled.
Catalogue numbers of waste types are to be assigned by the user upon the product application used and other facts.

European Waste Catalogue (EWC): **18 01 07**
Packaging: **15 01 01, 15 01 02**
Waste from cleaning: **15 02 03**

Legal regulations relating to waste

Directive on waste 2006/12/EC and 2008/98/EC. Disposal must be made according to official regulations.
Dispose of the waste in accordance with local (national) regulations.

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 available.

14.3 Transport hazard class(es)

Not available.

14.4 Packing group

Not available.

14.5 Environmental hazards

Not available.

14.6 Special precautions for user

See section 4 to 8.

14.7 Maritime transport in bulk according to IMO instruments

Not available.

Section 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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, as amended.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 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 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

15.2 Chemical safety assessment

Not available.

Section 16 OTHER INFORMATION

Revision: SDS_0089_A02_1.0

Standard and supplementary hazard statements used in the safety data sheet

Not applicable.

Precautionary statements used in the safety data sheet

Not applicable.

Training Advice

The person working with the product must be demonstrably trained.

History of document changes

Change in the ID format (from DOK to SDS)

New template according to Regulation (EC) No. 1907/2006 (REACH), amended by Regulation (EU) 2020/878.

Abbreviations and acronyms

ATE	Acute toxicity estimated
BCF	Bio-concentration factor
DMEL	Derived minimal effect level
DNEL	Derived no-effect level
LC50	Lethal concentration
LD50	Lethal dosis
NBR	Nitril butadien rubber
NPK-P	Maximum permissible concentration
PBT	Persistent, bioaccumulative and toxic
vPvB	Very persistent and very bioaccumulative
PEL	Permissible exposure limit
PNEC	Predicted no effect concentration
STEL	Short-term exposure limit
SVHC	Substance of very high concern
TWA	Time-weighted average

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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