

SAFETY DATA SHEET

GeneProof Pathogen Free DNA Isolation Kit

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

1.1 Product identifier

in vitro diagnostic medical devices
GeneProof PathogenFree DNA Isolation Kit

REF: IDNA250, IDNA050

Brand: GeneProof a.s.

Index-No: Not applicable

REACH No.: Not applicable

CAS-No: Not applicable

Synonyms, commercial names- IDNA250, IDNA050

In accordance with 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 is manufactured in accordance with requirements of European Parliament and Council directive 98/79/EC, on *in vitro* diagnostic medical devices requirements.

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

Product is use for column isolation of DNA

1.3 Details of the supplier of the safety data sheet

Manufacturer: GeneProof a.s.
Videňská 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

Classification of the product:

Pictogram (GHS):



Signal word: Danger

Classification (GHS): H225 Flam Liq 2
H302 Acute Tox 4
H315 Skin Irrit 2
H319 Eye Irrit 2
H334 Resp Sens 1A/1B
H336 STOT SE 3

2.1 Classification of the substance or mixture

Classification in compliance with EU directive 1272/2008.

List of phrases is written in chapter 16.

B3: Guanidine hydrochloride 36 - 50 %

Klasifikace (GHS): Acute Tox. 4 H302
Eye Irrit 2 H319

Proteinasa K: Proteinase K 100 %

Klasifikace (GHS): Resp. Sens. 1 H334
Skin Irrit. 2 H315
Eye Irrit. 2 H319

BW: 2-propanol 20 – 50 %

Klasifikace (GHS): Flam. liq. 2 H225
Eye Irrit. 2A H319
STOT SE 3 H336

The others components (Buffer B5, Buffer BE, buffer for proteinase BP, DNA collums and centrifugation tubes)) of the product are without well-known risk.

2.2 Label elements

Valid for B3:

Signal word: Warning
H-phrases: H302, H319

Pictogram:



Valid for BW:

Signal word: Danger
H-phrases: H225, H319, H336

Pictogram:



Valid for Proteinase K:

Signal word: Danger

Pictogram:



H-phrases: H334, H315, H319

The others components (Buffer B5, Buffer BE, buffer for proteinase BP, DNA collums and centrifugation tubes) of the product are without well-known risk

2.3 Other hazards

Flammable products. Vapour forms explosive mixtures with air.

SAFETY DATA SHEET

GeneProof Pathogen Free DNA Isolation Kit

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Proteinase K (1 - 75 mg):

Chemical: Proteinase K
Concentration: 90 - <100 %
Origin: Tritirachium album
CAS No: 9001-92-7
Index No: -
EC No.: 232-642-4
GHS (CLP) see section 2, section 16

PB (1,8 ml):

Chemical: Glycerol
Concentration: 10 - < 50 %
Pseudonym: Glycerin, 1,2,3-propanetriol
Formula: $C_3H_8O_2$
CAS No: 56-81-5
EC No.: 200-289-5

Other substances (Buffer B5, Buffer BE, buffer for proteinase BP, DNA collums and centrifugation tubes) - not applied

3.2 Mixtures

B3 (15 ml):

Chemical: Guanidine hydrochloride
Concentration: 36 - < 50 %
Formula: CH_6ClN_3
Pseudonym: Guanidinium chloride
CAS No: 50-01-1
Index No.: 607-148-00-0
EC No.: 200-002-3

Chemical: Polyoxyethylene sorbitan monolaurate (Tween® 20)
Concentration: 10 - < 33 %
Formula: $C_{58}H_{114}O_{26}$
Pseudonym: Sorbitan, monododekanát
CAS No.: 9005-64-5

BW (30 ml):

Chemical: 2-propanol
Concentration: 20 - < 35 %
Formula:
Pseudonym: Isopropanol, propan-2-ol
CAS No.: 67-63-0
Index No.: 603-117-00-0
EC No.: 200-661-7

Chemical: Guanidine hydrochloride
Concentration: 36 - < 50 %
Formula: CH_6ClN_3
Pseudonym: Guanidium chloride
CAS No.: 50-01-1
Index No.: 607-148-00-0
EC No.: 200-002-3

GHS (CLP) see section 2, section 16

Other information: for the full texts of hazard phrases see section 16.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

General notes

Place injured person out of danger zone to fresh air immediately. Ensure quiet, warmth, and provide resuscitation if necessary. If necessary contact medical advice.

Inhalation

After inhalation of foam or vapour fresh air should be inhaled. Keep airways free. Administer a Dexamethasone spray as soon as possible. Ensure quiet, warmth, and provide resuscitation if necessary. In the event of respiratory distress ensure that the patient inhales oxygen. Secure the breathing, heart and circulatory function.

Skin contact

Remove contaminated clothing immediately. Rinse the affected skin or mucous membrane thoroughly for min. 15 minutes under running water, if possible, use soap. Avoid neutralisation. Then apply a loose bandage

Contact with eyes

After contact with the eyes rinse thoroughly under running water with the eyelid wide open with eye washing bottle, eye douche or running water (protect intact eye).

Swallowing

After oral intake lots of water should be drunk after it has been ingested.

First aider protection

Not necessary.

4.2 Most important symptoms and effects, both acute and delayed

Chronic Effects: May cause sensitization by skin contact, also in repeated contact of small amounts. May cause allergy, asthma symptoms or breathing difficulties if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

After SKIN CONTACT rinse with water for a long time. Apply glucocorticosteroides following inflammatory reactions.

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Appropriate extinguishing: foam, water spray, dry powder, carbon dioxide, water stream

Inappropriate extinguishing: none

5.2 Special hazards arising from the substance or mixture

WARNING: Flammable (GHS regulation). May form explosive vapour-air mixtures. Formation of hazardous and caustic vapour-air mixtures possible.

5.3 Advice for firefighters

Not for listed product. Product package burns like paper or plastic. Spray any vapours released with water. Use only acid-resistant safety equipment. For great amount - if necessary - protective breathing apparatus which is independent of the ambient air (isolated equipment), and sealed protective clothing is necessary in the event of a large-scale formation of toxic substances.

5.4 Other information

No information available.

SAFETY DATA SHEET

GeneProof Pathogen Free DNA Isolation Kit

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Do not breathe vapours. Wear suitable protective gloves. Wear eye protection. Regular staff training is necessary, indicating hazards and precautions on the basis of operating instructions.

6.2 Environmental precautions

Not necessary.

6.3 Methods and materials for containment and cleaning up

Bind any escaping liquid with inert absorbent. And dispose in accordance to local regulations for the disposal of hazardous chemicals. Clean any contaminated equipment and floors with plenty of water. Collect small amounts of leaked liquid and flush with water into drains.

6.4 Reference to other sections

See section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in accordance with the test instruction that comes with the product. Use only in well-ventilated working areas. In areas of use and storage must be avoided smoking, drinking and eating. For personal protection see section 8. Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature: see label.

Keep container tightly closed in a dry and well ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Observe label precautions. Protect containers from the effects of high temperatures. Electrical installations/working materials must comply with the technological safety standards. See package insert or internal guidelines. No decomposition if stored and applied as directed.

7.3 Specific end use

Laboratory chemicals.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

B3: Chemical: Guanidine hydrochloride

CAS No.: 50-01-1

Chemical: Polyoxyethylene sorbitan monolaurate (tween ®20)

CAS No.: 9005-64-5

BW: Chemical: Guanidine hydrochloride

CAS No.: 50-01-1

Chemical: 2-propanol

CAS No.: 67-63-0

DNEL: 500 inh mg/m³

DNEL = Derived No-Effect Level

PNEC (f resh water): 140.9 mg/L

PNEC = Predicted No Effect Concentration

Short term exposure factor: 2 (II), Y

skin resorptive (H), respiratory sensitive (Sa), ski sensitive (Sh), teratogenic (Z) not securely excluded/(Y) certainly exclude

SUVA(CH) MAK value: 200 ppm / 500 mg/m³

BP: Chemical: glycerol

C. CAS: 56-81-5

DNEL: 56 mg/m³

DNEL = Derived No-Effect Level

PNEC (f resh water): 0.885 mg/L

PNEC = Predicted No Effect Concentration

Short term exposure factor: 2 (I), Y

skin receptive (H), respiratory sensitizable (Sa), ski sensitizable (Sh), teratogenic (Z) not securely excluded/(Y) certainly exclude

SUVA(CH) MAK value: 50 e* mg/m³

Proteinase K (Iyo): Chemical: p roteinase K (origin: tritirachium album)

CAS No.: 9001-92-7

SUVA(CH) MAK value: 0,00006 15min mg/m³

8.2 Exposure control

Good ventilation and extraction system in the room, floor resistant to chemicals with floor drainage and washing facilities. The highest level of cleanliness must be maintained at the workplace.

Personal exposure control

Eye/face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand protection

Gloves according EN 374 (permeation time >30 min - level 2), consist of PVC, natural latex, Neopren, or Nitril (for exampple. Ansell or KCL). Use for short times chemical resistant latex gloves with code EN 374-3 level 1.

Respiratory protection

No more recommendation.

SAFETY DATA SHEET

GeneProof Pathogen Free DNA Isolation Kit

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. Rinse any clothing on which the substance has been spilled, and soak it in water. Wash hands thoroughly with soap and water when stopping work and before eating, and then apply protective skin cream.

Environmental exposure controls

Not applied.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

B3
Appearance: Liquid
Colour: Slightly yellow
Odour: Odourless
pH: 3,5-4
Specific gravity: 1,15g/cm³

B5
Appearance: Liquid
Colour: Colourless
Odour: Odourless
pH: 7 - 8
Specific gravity: 1,0 g/cm³

BE
Appearance: Liquid
Colour: Colourless
Odour: Odourless
pH: 8 - 9
Specific gravity: 1,0 g/cm³

BW
Appearance: Liquid
Colour: Colourless
Odour: Alcoholic
pH: 7 - 8
Flash point: 25 °C
Specific gravity: 1,06 g/cm³

Proteinasa K
Appearance: Solid
Colour: Slightly grey
Odour: Odourless

PB
Appearance: Liquid
Colour: Colourless
Odour: Alcoholic
Specific gravity: 1,11 g/cm³

Unlisted physical-chemical 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

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

Data not available.

10.2 Chemical stability

Stable under storage conditions.

10.3 Possibility of hazardous reactions

Guanidine hydrochloride – Violent reaction with strong acids and oxidants.

10.4 Conditions to avoid

Not necessary.

10.5 Incompatible materials

Avoid contact with strong acids or alkalines.

10.6 Hazardous decomposition products

In the original package all parts/all reagents are safety and separated stored. Decompositions are not observed during the expiration period under recommended conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

B3
Chemical: Guanidine hydrochlorid
CAS No.: 50-01-1
LD50 orl rat: 475 mg/kg
LC50 ihl rat: 5,3 _{4h} mg/m³
LD50 drl rbt: >2000 mg/kg
Acute effects: Cause after oral intake, impairments of health when ingested in small quantities

Chemical: Polyoxyethylen sorbate monolaurate (Tween® 20)
CAS No.: 9005-64-5

BW
Chemical: Guanidine hydrochloride
CAS No.: 50-01-1
LD50 orl rat: 475 mg/kg
LC50 ihl rat: 5,3 _{4h} mg/m³
LD50 drl rbt: >2000 mg/kg
Acute effects: Cause after oral intake, impairments of health when ingested in small quantities

Chemical: 2-propanol
CAS No.: 67-63-0
LD50 orl rat: 5045 mg/kg

SAFETY DATA SHEET

GeneProof Pathogen Free DNA Isolation Kit

LC₅₀ orl hm: 3570 mg/kg
LC₅₀ ihl rat: 16th g/m³
LD₅₀ drl rbt: 12.8 g/kg
Acute effects: Cause after oral intake, impairments of health when ingested in small quantities.

PB
Chemical: Glycerol
CAS No.: 56-81-5
LD₅₀ orl rat: 12.6 g/kg
LD₅₀ drl rbt: >18.7 g/kg
Acute effects: Cause after oral intake, impairments of health when ingested in small quantities

Proteinase K
Chemical: Proteinase K (triturachium album)
CAS No.: 9001-92-7
Acute effects: Cause after oral intake, impairments of health when ingested in small quantities.
Chronic effects: May cause sensitization by skin contact, also in repeated contact of small amounts. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Other components (buffer B5, buffer BE, buffer Proteinase PB, DNA columns a centrifugation tubes) 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: Data are not available.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

BW
Chemical: Guanidine hydrochloride
CAS No.: 50-01-1
LC₅₀ leuciscus idus/96h : 1759 mg/L
WGK No.: 0788
Storage class (VCI): 12

Chemical: 2-propanol
CAS No.: 67-63-0
PNEC (fresh water) : 140,9 mg/L
PNEC = Predicted No Effected Concentration
LC₅₀ fish/96h : 1400 mg/L
EC₅₀ daphnia/48h : 13.3 g/L
IC₅₀ scenedesmus quadricauda/72h: >1000 mg/L
EC₁₀ pseudomonas putita/16h: EC₅: 1050 mg/L
Dispersion coefficient (octanol-water): 0.05
Storage class (VCI): 3

PB
Chemical: Glycerol
CAS No.: 56-81-5
PNEC (fresh water): 0.885 mg/L
P NEC = Predicted No Effected Concentration
LC₅₀ fish/96h : >5000 24h mg/L
EC₅₀ daphnia/48h : >10 24h g/L
IC₅₀ scenedesmus quadricauda/72h: IC₅ 7d >10 g/L
EC₁₀ pseudomonas putita/16h: EC₅: >10 g/L
Dispersion coefficient (octanol-water): 1.76
Storage class (VCI): 10

Proteinase K
Chemical: Proteinase K
CAS No.: 9001-92-7
Storage class (VCI): 13

Other components (buffer B5, buffer BE, buffer Proteinase PB, DNA columns a centrifugation tubes) of medical device *in vitro* are not declaration necessary.

12.2 Persistence and degradability

Not necessary.

12.3 Bio accumulative potential

Not necessary.

12.4 Mobility in soil

Not necessary.

12.5 Results of PBT and vPvB assessment

Data not available.

12.6 Other adverse effects

Guanidine hydrochloride: Water hazard class 1 (light water hazard)

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Prevent entry into drains. Minimize waste. Remove in accordance with local and national regulations. Recycle packaging until they clean up and recycle according to the regulations. Waste is disposed of each authorized person (a company specializing in waste disposal). Waste code: 16 05 06 (laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals).

Recommended cleaning agent: Normally it is possible to empty small amounts (diluted!) into drains. Waste code is valid for European Union. If you are not in EU see your own national regulations.

SECTION 14. TRANSPORT INFORMATION

14.1 UN Number

1993

14.2 UN Proper shipping name

Flammable liquid, n.o.s. (2-propanol mixture).

14.3 Transport hazard class

3.

14.4 Packing group

III

SAFETY DATA SHEET

GeneProof Pathogen Free DNA Isolation Kit

Road transport:

Classification code: F1
Limited Quantity: 5 L
Tunnel restriction code: E
Excepted Quantity: E 1
Special instructions: 640E

Air transport:

PAX: 355 max. weight PAX: 60 L
CAO: 366 max. weight CAO: 220 L

Maritime transport:

EmS: F-E, S-E
Storage category: A

14.5 Environmental hazards

Not necessary, contains only small amounts of hazardous substances.

14.6 Special precautions for user

Not necessary.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

SECTION 15. REGULATORY INFORMATION

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

In accordance with 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, according to article 31, paragraph 1.

This CE IVD product does not apply The Regulation (EC) No. 1272/2008 of the Europe Parliament and of the Council, according to article 1, paragraph 5.

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

15.2 Chemical safety assessment

Not applicable for the product.

SECTION 16. OTHER INFORMATION

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

H225 Highly flammable liquid and vapour
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H336 May cause drowsiness or dizziness.

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

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking
P261 Do not breathe vapours.
P273 Avoid release to the environment.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents with accordance with local legislation.

16.3 Training Advice

The staff must be trained and the training must be verifiably.

16.4 List of changes of the document

Change list of the document is available on request by GeneProof, a.s.
Reason for change: Revision 02: Appendix is divided into Czech and English version.

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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