

# SAFETY DATA SHEET

## GeneProof Pathogen Free RNA 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 RNA Isolation Kit

REF GeneProof a.s.: IRNA250, IRNA050  
Brand: GeneProof a.s.  
Index-No: Not applicable  
REACH No.: Not applicable  
CAS-No: Not applicable  
Synonyms, commercial names- IRNA250, IRNA050

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

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

Product is use for column isolation of RNA

#### 1.3 Details of the supplier of the safety data sheet

Manufacturer: GeneProof a.s.  
Václavská 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: Warning

Classification (GHS): H225 Flam liq 2  
H302 Acute Tox 4  
H412 Aquatic Chronic 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.

RAV1: Guanidine thiocyanate 30 – < 60 %  
Classification (GHS): AcuteTox 4 H302  
AquaticChronic 3 H412

RAW: Guanidine hydrochloride 24 - < 36 %  
Classification (GHS): Acute Tox. 4 H302  
Skin Irrit 2 H315  
Eye Irrit 2A H319

Ethanol 35 – 55 %  
Classification (GHS): Flam liq 2 H225

The others components (buffer RAV3, RNase-free-H<sub>2</sub>O, pufr RE, carrier RNA, RNA column, centrifuge test tube) of the product are without well-known risk.

#### 2.2 Label elements

Valid for RAV1:

Pictogram (GHS):



Signal word: Danger

H-phrases: H302+ H312 + H332, H412

Valid for RAW:

Pictogram:



Signal word: Danger

H-phrases: H302, H315, H319, H225

#### 2.3 Other hazards

None or not determined.

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### SECTION 3. COMPOSITION/INFORMACITON ON INGREDIENTS

#### 3.1 Substances

<b>RAV1:</b>		<b>RNAse-free H<sub>2</sub>O:</b>		<b>carrier RNA:</b>
Chemical:	Guanidine Thiocyanate	Chemical:	water	Chemical: -
Concentration:	30 – < 60 %	Concentration:	90 – < 100 %	Concentration: 90 – < 100 %
Formula:	C <sub>2</sub> H <sub>6</sub> N <sub>4</sub> S	Formula:	H <sub>2</sub> O	CAS No: 26763-19-6
Pseudonym:	Guanidine Isothiocyanate	CAS No:	7732-18-5	
CAS No:	593-84-0			
Index No:	615-004-00-3			
EC No.:	209-812-1			
GHS (CLP)	see section 2, section 16			

buffer RAV3, pufr RE, RNA column, centrifuge test tube - non applied

#### 3.2 Mixtures

<b>RAW:</b>			
Chemical:	Guanidine hydrochloride	Chemical:	Ethanol
Concentration:	24 – < 36 %	Concentration:	35 – < 55 %
Formula:	CH <sub>5</sub> ClN <sub>3</sub>	Formula:	CH <sub>3</sub> CH <sub>2</sub> OH
Pseudonym:	Guanidinium chloride	Pseudonym:	Ethyl alcohol
CAS No:	50-01-1	CAS No:	64-17-5
Index No.:	607-148-00-0	Index No.:	603-002-00-5
EC No.:	200-002-3	EC No.:	200-578-6
GHS (CLP)	see section 2, section 16	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

In the case of the occurrence of any symptoms or in doubt, consult health status with your doctor. When unconscious do not give oral products.

##### Aspiration

After inhalation of foam or vapour fresh air should be inhaled. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Keep airways free. If experiencing respiratory symptoms: call a poison centre/doctor.

##### Skin contact

Remove contaminated clothing. Rinse the affected skin or mucous membrane thoroughly under running water. (If possible) use soap. If the symptoms persist, call a doctor.

##### 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

Clean mouth with water and drink afterwards plenty of water. Keep respiratory tract clear. Do NOT induce vomiting. Never give anything to mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital. If experiencing respiratory symptoms: call a poison centre/doctor (get medical advice/attention).

##### 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

If the symptoms persist: call a poison centre.

### SECTION 5. FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

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

#### 5.2 Special hazards arising from the substance or mixture

Do not allow the mixture run-off from fire fighting to enter drains or water courses. The component RAV1 releases a toxic gas at boiling point.

#### 5.3 Advice for firefighters

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.

Use alcohol resistant foam, carbon dioxide, or dry chemical when fighting hazardous component. Water or foam may cause frothing, but it still may be a useful extinguishing agent if carefully applied to the surface of the fire. Do not use a stream of water. Use water spray for cooling.

Do not allow the water run-off to drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Refer to protective measures listed in sections 7 and 8. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas

#### 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

Use personal protective equipment. Ensure adequate ventilation. Remove all sources of ignition. Regular staff training is necessary.

#### 6.2 Environmental precautions

Prevent product from entering drains. Prevent further leakage or spillage. Harmful to aquatic life with long lasting effect.

#### 6.3 Methods and materials for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see section 13).

#### 6.4 Reference to other sections

See section 8 and 13.

### SECTION 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Avoid formation of aerosol. Do not breathe vapours/dust. Avoid exposure, 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. 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

Carrier RNA: Chemical: carrier RNA

CAS No: 26763-19-6

RAV1: Chemical: guanidine thiocyanate

CAS No: 593-84-0

RAW: Chemical: guanidine hydrochloride

CAS No: 50-01-1

Chemical: ethanol

CAS No: 64-17-5

RNAse free: Chemical: water

CAS No: 7732-18-5

Ethanol CAS No: 64-17-5

Limit value - Eight hours

Limit value - Short term

State (legislation)	ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>
<a href="#">Australia</a>	1000	1880		
<a href="#">Austria</a>	1000	1900	2000	3800
<a href="#">Belgium</a>	1000	1907	-	-
<a href="#">Canada - Ontario</a>	-	-	1000	-
<a href="#">Canada - Québec</a>	1000	1880	-	-
<a href="#">Denmark</a>	1000	1900	2000	3800
<a href="#">Finland</a>	1000	1900	1300 (1)	2500 (1)
<a href="#">France</a>	1000	1900	5000	9500
<a href="#">Germany (AGS)</a>	500	960	1000 (1)	1920 (1)
<a href="#">Germany (DFG)</a>	500	960	1000 (1)	1920 (1)
<a href="#">Hungary</a>	-	1900		7600
<a href="#">Ireland</a>	-	-	1000 (1)	-
<a href="#">Latvia</a>	-	1000	-	-
<a href="#">New Zealand</a>	1000	1880	-	-
<a href="#">Poland</a>	-	1900	-	-
<a href="#">Singapore</a>	1000	1880	-	-
<a href="#">South Korea</a>	1000	1900	-	-
<a href="#">Spain</a>			1000	1910
<a href="#">Sweden</a>	500	1000	1000 (1)	1900 (1)
<a href="#">Switzerland</a>	500	960	1000	1920
<a href="#">The Netherlands</a>		260	-	1900
<a href="#">USA - NIOSH</a>	1000	1900	-	-
<a href="#">USA - OSHA</a>	1000	1900	-	-
<a href="#">United Kingdom</a>	1000	1920	-	-

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### 8.2 Exposure control

#### 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 example. Ansell or KCL). Use for short times chemical resistant latex gloves with code EN 374-3 level 1.

##### Respiratory protection

No more recommendation.

##### Skin and body protection

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

##### Osobní hygiena

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.

#### Enviromental exposure controls

Do not let product enter drains.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

#### Carrier RNA

Appearance: Solid (lyoph.)

Colour: Colourless

Odour: Odourless

pH: 8

Density/Specific gravity: Not determinate

Melting point: 0 °C

Boiling point: 100 °C

Solubility in water: not soluble

#### RNAse-free H<sub>2</sub>O

Appearance: liquid

Colour: Colourless

Odour: Odourless

pH: 6 - 8

Density/Specific gravity: 1,0 g/cm<sup>3</sup>

Melting/freezing point: 0 °C

Boiling point: 100 °C

Evaporation rate: 0,36 (butylacetate = 1)

Vapour pressure (20 °C): 3,2 kPa

Solubility: in water, methanol, acetone

Partition coefficient: -1,38 log log *K<sub>ow</sub>*

#### Lysis Buffer RAV1

Appearance: liquid

Colour: Colourless

Odour: Odourless

pH optimum: 4,8 - 6

Melting/freezing point: 118 – 122 °C

Density/Specific gravity: 1.29 g/cm<sup>3</sup>

#### Buffer RAV3 (concentrate)

Appearance: liquid

Colour: Colourless

Odour: Odourless

pH: 7 - 8

Density/Specific gravity: 1,120 g/cm<sup>3</sup>

Melting point: 0 °C

Boiling point: Not determinate

Vapour pressure (20 °C): 23 hPa

#### Buffer RE

Appearance: liquid

Colour: Colourless

Odour: Odourless

pH: 8 - 9

Density/Specific gravity: 1,0 g/cm<sup>3</sup>

#### Wash Buffer RAW

Appearance: liquid

Colour: Colourless

Odour: Alcohol odour

pH: 5 – 5.5

Density/specific gravity: 1.18 g/ml at 25 °C

Melting point: 180 – 185 °C

Solubility: in water: 2280 g/L (20 °C), ethanol (300g/l), and alcohol

Boiling point: 23 °C

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 thiocyanate – contact with acids liberate toxic gas

Guanidine hydrochloride – Violent reaction with strong acids and oxidants.

### 10.4 Conditions to avoid

Strong-oxidizing agents

### 10.5 Incompatible materials

Data not available.

### 10.6 Hazardous decomposition products

Carbon dioxide, Carbon monoxide, Nitrogen oxides, Hydrogen chloride

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

##### RAV1

Chemical: Guanidine thiocyanate  
CAS No.: 593-84-0  
LD50 orl rat : 593 mg/kg  
LC50 drl rbt : 2000 mg/m<sup>3</sup>  
LC50 ihl rat : 5.319<sub>4h</sub> mg/L  
LD50 ipr mus : 300 mg/kg  
Acute Effects: Cause after oral intake, impairments of health when ingested in small quantities.

##### RAW (mixture)

Chemical: Guanidine hydrochloride  
CAS No.: 50-01-1  
LD50 orl rat : 475 mg/kg  
LC50 ihl rat : 5.3<sub>4h</sub> mg/m<sup>3</sup>  
LD50 drl rbt : >2000 mg/kg  
Acute Effects: Cause after oral intake, impairments of health when ingested in small quantities.

Chemical: Ethanol  
CAS No.: 64-17-5  
LD50 orl rat : 6200 mg/kg  
LC<sub>Low</sub> ihl gpg : 21.9 g/m<sup>3</sup>  
LC<sub>Low</sub> orl hmn : 1400 mg/kg  
LC50 ihl mouse : 39<sub>4h</sub> g/m<sup>3</sup>  
LC50 ihl rat : 20<sub>10h</sub> g/m<sup>3</sup>  
LD50 drl rbt : 20 000 mg/kg  
Acute Effects: Cause after oral intake, impairments of health when ingested in small quantities

Other components (RE, RNase Free – H<sub>2</sub>O, RAV3, Carrier RNA) 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

##### RAW (mixture)

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

##### RAV1

Chemical: Guanidine thiocyanate  
CAS No.: 593-84-0  
Harmful to aquatic life with long lasting effects.  
WGK (DE): 3  
Storage class (VCI): 12

Chemical: Ethanol  
CAS No.: 64-17-5  
PNEC (sweet water): 0.96 mg/L  
*PNEC = Predicted No Effected Concentration*  
LC50 daphnia magna/48h: >100 mg/L  
LC50 pimephales promelas/96h : 13400 - 15100 mg/L  
LC50 leuciscus idus/96h : 8140 48h mg/L  
LC50 fish/96h : 13 g/L  
EC50 daphnia/48h : 9.3-14.2 g/L  
IC50 scenedesmus quadricauda/72h : 5000 7d mg/L  
EC10 pseudomonas putilla/16h : EC5: 6500 m  
WGK (DE): 1 number WGK: 0096  
Dispersion coefficient: -0.31  
Storage class. (VCI): 3

Other components (RE, RNase Free – H<sub>2</sub>O, RAV3, Carrier RNA) 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)

Guanidine thiocyanate: Water hazard class 2( hazardous for water). Do not allow product to reach ground water, water course or sewage system.



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### SECTION 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Prevent entry into drains. Minimize waste. Remove in accordance with local and national regulations. Fire in a hazardous waste incinerator. 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. (ethanol (denatured ethanol) mixture).

#### 14.3 Transport hazard class

3.

#### 14.4 Packing group

III

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 quantities of hazardous substances, contains only small amounts of these substances S

#### 14.6 Special precautions for user

Not necessary.

#### 14.7 Transport in bulk according to Annex II of MARPOL 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 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, 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 product is for *in vitro* diagnostics 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+H312+H332 Harmful if swallowed, in contact with exes, or if inhaled.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects

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

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking  
P260D Do not breathe vapours.  
P273 Avoid release to the environment.

#### 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 03: Appendix is divided into Czech and English version.

Revision 04: Percentage correction, section 3

#### 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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