

 Genmark Sağlık Ürünleri ITH. İHR SAN. TIC. LTD.	Technical File	Docum No: F-19-01
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1. Product and Company Identification

1.1 Product identifier

Product Name	geneMAP™ Thrombophilia Panel, 50T (FII, FVL, MTHFR 677, MTHFR 1298, PAI& FXIII)
Cat. No.	THR6-RT50
Composition	Master Mix - FII-Protrombin
	Master Mix - FV-Leiden
	Master Mix - MTHFR-C677T
	Master Mix - MTHFR A1298C
	Master Mix - PAI-1 FAM:4G/VIC:5G
	Master Mix - FXIII-V34L
	Thrombophilia Heterozygous PC
	Thrombophilia Homozygous PC

1.2 Recommended use of the products and restrictions on use

For *in vitro* diagnostic use only

1.3 Manufacturer/Supplier Information

Genmark Sağlık Ürünleri İth. İhr. Tic. Ltd. Sti.

Halil Rifat Paşa Mah. Güler Sk. GNM Plaza No:51-1 34384 Okmeydanı/Şişli-İSTANBUL-TURKEY

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2. Hazards Identification

2.1 Hazards·Risk Classification

Acute toxicity-Oral	Category 4
Skin sensitization	Category 1

2.2 Label elements including precautionary statements

Emergency Overview

Symbol



Signal word

Warning

Hazard·Risk statements

H302- Harmful if swallowed
H315- Causes skin irritation
H319- Causes serious eye irritation
H335- May cause respiratory irritation

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Precautionary statements

- P201- Obtain special instructions before use.
- P261- Avoid breathing dust/fumes/gas/mist/vapours/spray.
- P264- Wash skin thoroughly after handling.
- P270- Do not eat, drink or smoke when using this product.
- P272- Contaminated work clothing should not be allowed out of the workplace.
- P280- Wear protective gloves/protective clothing/eye protection/face protection.
- P301+P312- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P302+P352- IF ON SKIN: Wash with plenty of water
- P330- Rinse mouth.
- P333+P313- If skin irritation or a rash occurs: Get medical advice/attention.
- P363- Wash contaminated clothing before reuse.
- P405- Store locked up.
- P401- Store properly in accordance with relevant regulation.
- P501- Dispose of contents/container in accordance with local, regional, national and/or international regulation.

Other Hazard/Risk which are not included in the classification criteria

None

3. Composition/Information on Ingredients

- Master Mix - FII-Protrombin

INGRIDENTS	CAS #	PERCENT
Mixture of Oligodeoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Master Mix - FV-Leiden

INGRIDENTS	CAS #	PERCENT
Mixture of Oligodeoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Master Mix - MTHFR-C677T

INGRIDENTS	CAS #	PERCENT
Mixture of Oligodeoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Master Mix - MTHFR A1298C

INGRIDENTS	CAS #	PERCENT
Mixture of Oligodeoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Master Mix - PAI-1 FAM:4G/VIC:5G

INGRIDENTS	CAS #	PERCENT
Mixture of Oligodeoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Master Mix - FXIII-V34L

INGRIDENTS	CAS #	PERCENT
Mixture of Oligodeoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Thrombophilia Homozygous PC

INGRIDENTS	CAS #	PERCENT
Mixture of Deoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

- Thrombophilia Heterozygous PC

INGRIDENTS	CAS #	PERCENT
Mixture of Deoxyribonucleic Acid	N/A	<1%
Trizma base	77-86-1	<1%
Ethylenediaminetetraacetic acid	6381-92-6	<1%
Water	7732-18-5	70~99%

The composition is a mixture of the non-hazardous substances. The exact concentration percentages of the non-hazardous substances may be withheld as a Genmark Sağlık Corp. trade secret.

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THIS PRODUCT IS CONSIDERED NON-HAZARDOUS.

This product does not contain more than 1% of a component classified as hazardous and does not contain more than 0.1% of a component classified as carcinogenic. Despite the classification of certain products/components as non-hazardous, we strongly recommend using prudent laboratory practices: avoiding unnecessary contact and use of personal protective equipment, which may include gloves, eye protection, and lab coats, during the use of any laboratory reagent.

4. First Aid Measures

- Skin Contact:** Remove contaminated clothing. Flush affected with water and then wash with soap or mild detergent and water. Observe for signs of irritation. If irritation is present, get medical attention.
- Eye Contact:** Wash eyes with large amounts of water or normal saline for at least 15 minutes. Observe for signs of irritation. If irritation is present, get medical attention.
- Ingestion:** Get medical attention.
- Inhalation:** Remove from exposure area to fresh air immediately. Get medical attention immediately.
- Injection:** If accidentally injected, get medical attention.
- Note to Physician:** There is no specific antidote. Treat symptomatically and supportively.

5. First Fighting Measures

- Fire and Explosion Hazard:** None known to exist
- Fire Extinguishing Media:** Dry chemical, foam, carbon dioxide or water. Care should be taken as to not aerosolize the powder, where it could become an inhalation risk.

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6. Accidental Release Measures

Occupational Spill: Wear appropriate protective clothing and chemically compatible gloves. Place spillage in appropriate container for waste disposal. Was contaminated clothing before reuse.

Reportable Quantity (RQ): Not Applicable

7. Handling and Storage

Observe all federal, state and local regulations. Do not breathe dust. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Keep tightly closed. The components of the product should be stored at -20°C. Use prudent laboratory practices for handling and storage of chemical substances of unknown toxicity.

8. Exposure Controls/Personal Protection

Exposure Controls: Use in a laboratory hood or other ventilated device. OSHA, ACGIH, or NIOSH has not established occupational exposure limits for this substance. Use prudent laboratory practices for handling chemical substances of unknown toxicity.

Eye Protection: Employees should wear splash proof or dust resistant safety goggles to prevent eye contact with this substance.

Clothing: Employees should wear appropriate protective clothing (laboratory coat with long sleeves) and equipment to prevent skin contact with this material.

Gloves: Employee must wear appropriate protective gloves to prevent contact with this material.

9. Physical and Chemical Properties

Description: Translucent or opaque flake, film or powder like substance

pH: Not Available

10. Stability and Reactivity

Reactivity: No adverse reactions have been reported.

Conditions to Avoid: Prolonged Storage. Keep at $\leq -20^{\circ}\text{C}$.

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Incompatibilities: Not Available

Polymerization: Not Available

11. Toxicological Information

Toxicity: No Known significant effects or critical hazards.

Carcinogen Status: No information available.

Local Effects: No information available.

Target Effects: No information available.

At Increased Risk from Exposure: No information available.

12. Ecological Information

Environmental Impact Rating (0-4): No data available.

Acute Aquatic Toxicity: No data available.

Degradability: No data available.

Log Bioconcentration Factor (BCF): No data available.

13. Disposal Considerations

Observe All Federal, State and Local Regulations.

14. Transportation Information

Not regulated Non-hazardous for transport: This substance is considered to be non-hazardous for transport.

15. Regulatory Information

OSHA Hazards: None known.

US Classification and Label Test

US Statements: Caution. Avoid contact and inhalation.

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Sara Listed: No

TSCA Inventory Item: Yes

European information

Caution : substance not yet fully tested.

R : 36/37/38

Irritating to eyes, respiratory system and skin.

R : 36/37/39

Wear suitable protective clothing, gloves and eye/face protection

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

[EU Regulation (EC) No. 1907/2006 (REACH)]

Annex XIV (List of substances subject to authorization): None of the components are listed.

Substances of very high concern: None of the components are listed.

Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles): Not applicable.

16. Other Information

The aforementioned information is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. *Genmark Sağlık* shall not be held liable for any damage resulting from handling or from contact with the above product.