

Safety data sheet

According to Annex II of Regulation (EC) No 1907/2006

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name	Product REF	Product Basic UDI-DI/GMDN
TPA RUO	1020GL	15999862992061
TPA	1021EU	59998629921021EU_1TG

Product form: mixture

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

Use of the Mixture: Ready to use reagent for the examination of the coagulation system in citrated blood.

1.3 Details of the supplier of the safety data sheet

APIRO Diagnostics Kft.
Liget utca 3/2, HU-2040 Budaörs, Hungary
<https://www.apiro.eu> / info@apiro.eu / +36 30 203 3334

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Not classified

2.2 Label elements

Labelling according to GHS	Not applicable
Hazard pictograms	Not applicable
Signal word	Not applicable
Hazard-determining components of labelling	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable

2.3 Other hazards

This product, as with all in vitro diagnostic tests analyzing blood, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

Section 3. Composition/information on ingredients

3.1 Substances

Item	CAS Nr.	Proportion (weight)
Reagent carrier (polypropylene)	9003-07-0	>99%
Calcium chloride	10043-52-4	<0.1-0.01%
Recombinant Tissue Factor	n/a	<0.001%
Fuch sine	632-99-5	<0.001%
Polybrene	28728-55-4	<0.01-0.001%
Alteplase	105857-23-6	<0.001%

3.2 Mixtures

Not applicable

Section 4. First aid measures

Not applicable due to the type, size and components of the product

Section 5. Firefighting measures

Not applicable due to the type, size and components of the product

Section 6. Accidental release measures

Not applicable due to the type, size and components of the product

Section 7. Handling and storage

Temperature requirements +2 to +8 °C

Section 8. Exposure controls/personal protection

Not applicable due to the type, size and components of the product

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical State	Solid
Appearance	Pipette tip with reagent carrier
Odor	No data available
pH	Not applicable (solid)

9.2 Other information

No additional information available

Section 10. Stability and reactivity

10.1 Reactivity

Hazardous reactions will not occur under normal conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

Direct sunlight, extremely high temperatures.

10.5 Incompatible materials

Not identified

10.6 Hazardous decomposition products

Not expected to decompose under ambient conditions.

Section 11. Toxicological information

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

Acute Toxicity (Oral)	Not classified
Acute Toxicity (Dermal)	Not classified
Acute Toxicity (Inhalation)	Not classified
Skin Corrosion/Irritation	Not classified
Serious Eye Damage/Irritation	Not classified
Respiratory or Skin Sensitization	Not classified
Germ Cell Mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive Toxicity	Not classified
Specific Target Organ Toxicity (Single Exposure)	Not classified
Specific Target Organ Toxicity (Repeated Exposure)	Not classified
Aspiration Hazard	Not classified
Symptoms/Injuries After Ingestion	Ingestion may cause adverse effects
Chronic Symptoms	None known.

11.2 Information on other hazards

No other hazards identified

Section 12. Ecological information

12.1 Toxicity

Not established

12.2 Persistence and degradability

Not established

12.3 Bioaccumulative potential

Not established

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

Not established

12.6 Endocrine disrupting properties

Not established

12.7 Other adverse effects

Not established

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste disposal recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

Section 14. Transport information

Not applicable due to the type, size and components of the product

Section 15. Regulatory information

Not applicable due to the type, size and components of the product

Section 16. Other information

Provided information is based on the company's current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

This document conforms with the Commission Regulation (EU) 2020/878.