according to Regulation (EC) No 1907/2006 (REACH), Annex II, as amended by Regulation (EU) 2020/878

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier: Thrombin Generation Assay (TGA) Kit

Product number: K004 (kit; components listed in Section 3)

1.2 Relevant identified uses: Laboratory reagent kit for research use only: determination of biomaterial-induced thrombin generation.

Uses advised against: Not for use in diagnostic or therapeutic procedures. Not for human or veterinary use.

1.3 Details of the supplier of the safety data sheet: HaemoScan BV, Stavangerweg 23-23, 9723 JC Groningen, The Netherlands. Tel. +31 (0)50 737 0187; e-mail mail@haemoscan.com; www.haemoscan.com

1.4 Emergency telephone number: +31 (0)50 737 0187 (HaemoScan; office hours only). National Poisons Information Centre (NVIC), the Netherlands: +31 (0)88 755 8000 (for medical professionals only).

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Kit: The kit and its components are not classified as hazardous according to Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Hazard pictograms, signal word, hazard statements: None.

Supplemental information (K004-1, K004-2, K004-9): EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

2.3 Other hazards: The TGA plasma (K004-3) is modified human plasma; the donor blood was tested and found negative for anti-HIV-1/2, HBsAg, anti-HCV, Syphilis, HIV1 RNA, HBV DNA and HCV DNA. As no test method can completely exclude the presence of infectious agents, handle it as potentially infectious material (biosafety level 2). The thrombin (K004-1) is of human origin. Some components contain protein of bovine origin. No component meets the PBT/vPvB criteria or has endocrine-disrupting properties at 0.1% or more.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Code	Component	Hazardous ingredients	Classification (CLP)
K004-1	Thrombin, 7.5 U, in buffer, 2 × 75 µL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K004-2	Buffer A (phosphate buffer with BSA), 11 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K004-3	TGA plasma (modified human plasma, freeze-dried), 5 vials	None	Not classified
K004-4	Saline (NaCl solution), 5 mL	None	Not classified
K004-5	TGA reagent A (aqueous salt solution), 2 × 5 mL	None	Not classified
K004-6	TGA reagent B (coagulation reagent), 2 × 600 µL	None	Not classified
K004-7	Buffer B (Tris buffer), 2 × 30 mL	None	Not classified

Code	Component	Hazardous ingredients	Classification (CLP)
K004-8	Substrate (thrombin-specific chromogenic substrate), 2 × 0.6 mL	None	Not classified
K004-9	Stop solution (acidic aqueous solution), 6 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K004-10	Reference 1: low-density polyethylene (LDPE), 5 pieces	None (article)	Not applicable
K004-11	Reference 2: polydimethylsiloxane (PDMS), 5 pieces	None (article)	Not applicable
K004-12	Reference 3: medical-grade steel (MS), 5 pieces	None (article)	Not applicable

Only ingredients that must be declared under REACH Annex II, Section 3.2, are listed; concentrations are given as ranges. The kit does not contain sodium azide. The reference materials (K004-10 to K004-12) are articles and are not subject to classification. Components marked EUH208 contain a trace of an isothiazolinone preservative (CMIT/MIT) below the specific concentration limit for skin sensitisation (0.0015%).

For the full text of the hazard statements, see Section 16.

SECTION 4: First-aid measures

4.1 Description of first-aid measures

General: Move the person away from the source of exposure. If medical advice is needed, show this Safety Data Sheet to the doctor in attendance. In case of contact of material of biological origin with damaged skin or mucous membranes, or a needle-stick injury, follow the local procedure for exposure to potentially infectious material.

Eye contact: Rinse immediately with plenty of water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Seek medical advice if irritation persists.

Skin contact: Wash with soap and plenty of water. After contact with material of biological origin, disinfect the affected area.

Ingestion: Rinse mouth with water. Do not induce vomiting. Seek medical advice if you feel unwell.

Inhalation: Move to fresh air. Inhalation is not an expected route of exposure under normal conditions of use.

4.2 Most important symptoms and effects, both acute and delayed: No specific symptoms known. The principal hazard is the potential presence of infectious agents in material of human origin (see Section 2.3).

4.3 Indication of any immediate medical attention and special treatment needed: Treat symptomatically. Consider the potentially infectious nature of material of biological origin.

SECTION 5: Firefighting measures

5.1 Extinguishing media: Use extinguishing media appropriate to the surrounding fire (water spray, foam, dry chemical or carbon dioxide). No unsuitable extinguishing media are known.

5.2 Special hazards arising from the substance or mixture: The product is not flammable. Combustion may produce oxides of carbon and nitrogen.

5.3 Advice for firefighters: Wear self-contained breathing apparatus and protective clothing if necessary.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: Wear protective gloves, a laboratory coat and eye protection (see Section 8). Avoid contact with skin and eyes and avoid the formation of aerosols.

6.2 Environmental precautions: Do not allow undiluted product to enter drains or surface water.

6.3 Methods and material for containment and cleaning up: Absorb spilled liquid with absorbent material. Decontaminate the area with 70% ethanol or a freshly prepared 1:10 dilution of 5% sodium hypochlorite, allow sufficient contact time and rinse with water. Dispose of contaminated material as biological waste (see Section 13).

6.4 Reference to other sections: For personal protection see Section 8; for disposal see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling: Handle in accordance with good laboratory practice and biosafety level 2 precautions for material of human or animal origin. Do not pipette by mouth. Avoid contact with skin and eyes and the generation of aerosols. Do not eat, drink or smoke in the laboratory. Wash hands after handling.

7.2 Conditions for safe storage, including any incompatibilities: Store the kit at −20 °C. After first use, Buffer A, Buffer B, Saline and Stop solution may be stored at 2–8 °C. Keep containers tightly closed. Do not use the kit after the expiry date.

7.3 Specific end use(s): Laboratory research use as described in the kit manual.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters: No occupational exposure limits have been established for the components of this product.

8.2 Exposure controls

Engineering controls: General laboratory ventilation is sufficient. Use a biological safety cabinet for procedures that may generate aerosols of material of biological origin.

Eye/face protection: Safety glasses with side shields (EN 166).

Hand protection: Disposable nitrile gloves (EN ISO 374-1). Replace gloves immediately if contaminated or damaged.

Body protection: Laboratory coat.

Respiratory protection: Not required under normal conditions of use.

Environmental exposure controls: Do not allow undiluted product to enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Property	Value
Physical state	Liquids; freeze-dried powder (K004-3); solid reference materials (K004-10 to K004-12)
Colour	Colourless to slightly opalescent (solutions); pale yellow (freeze-dried plasma)
Odour	Odourless
Melting point/freezing point	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flammability	Not flammable
Lower and upper explosion limit	Not applicable

Property	Value
Flash point	Not applicable (aqueous solutions)
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
pH	6–8; Stop solution (K004-9) approx. 2
Kinematic viscosity	Not determined
Solubility	Miscible with water
Partition coefficient n-octanol/water (log value)	Not applicable (mixture)
Vapour pressure	Not determined
Density and/or relative density	Not determined (aqueous solutions approx. 1.0 g/cm³)
Relative vapour density	Not applicable
Particle characteristics	Not determined (freeze-dried plasma)

9.2 Other information: The TGA plasma is of human origin (see Section 2.3).

SECTION 10: Stability and reactivity

10.1 Reactivity: No hazardous reactions are known under normal conditions of use.

10.2 Chemical stability: Stable under the recommended storage conditions.

10.3 Possibility of hazardous reactions: None known.

10.4 Conditions to avoid: Heat and storage outside the recommended temperature range (loss of activity).

10.5 Incompatible materials: Strong oxidising agents.

10.6 Hazardous decomposition products: None known under normal conditions of use.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008: No toxicological studies have been performed on the kit. Based on the available data, the classification criteria are not met for any health hazard class. Skin sensitisation: some components contain a trace of an isothiazolinone preservative below the classification limit; they may produce an allergic reaction in sensitised persons (EUH208).

11.2 Information on other hazards

Endocrine-disrupting properties: No component is known to have endocrine-disrupting properties at a concentration of 0.1% or more.

Other information: The TGA plasma may contain infectious agents and must be handled as potentially infectious (see Section 2.3).

SECTION 12: Ecological information

12.1 Toxicity: No ecotoxicological data are available for the product. The components are not classified as hazardous to the aquatic environment.

12.2 Persistence and degradability: The biological components (proteins, cells) are readily biodegradable. No data are available for the other components.

12.3 Bioaccumulative potential: No potential for bioaccumulation is expected.

12.4 Mobility in soil: The liquid components are miscible with water.

12.5 Results of PBT and vPvB assessment: No component meets the PBT or vPvB criteria of REACH Annex XIII at a concentration of 0.1% or more.

12.6 Endocrine-disrupting properties: No component is known to have endocrine-disrupting properties at a concentration of 0.1% or more.

12.7 Other adverse effects: None known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods: Dispose of the product, its containers and contaminated materials as biological (potentially infectious) waste, e.g. by autoclaving or incineration, in accordance with local and national regulations.

SECTION 14: Transport information

The product is not classified as dangerous goods under ADR/RID, IMDG or IATA.

14.1 UN number or ID number: Not applicable

14.2 UN proper shipping name: Not applicable

14.3 Transport hazard class(es): Not applicable

14.4 Packing group: Not applicable

14.5 Environmental hazards: None

14.6 Special precautions for user: Ship at −20 °C or on dry ice. Fragile containers; handle with care. When shipped on dry ice, the outer packaging is marked UN 1845, Dry ice, class 9.

14.7 Maritime transport in bulk according to IMO instruments: Not applicable.

SECTION 15: Regulatory information

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

- Regulation (EC) No 1907/2006 (REACH).
- Regulation (EC) No 1272/2008 (CLP).
- Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work.
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for this product.

SECTION 16: Other information

Full text of hazard statements: EUH208 Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Abbreviations: ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road; CAS: Chemical Abstracts Service; CLP: Regulation (EC) No 1272/2008; IATA: International Air Transport Association; IMDG: International Maritime Dangerous Goods Code; PBT: persistent, bioaccumulative and toxic; REACH: Regulation (EC) No 1907/2006; RID: Regulations concerning the International Carriage of Dangerous Goods by Rail; SVHC: substance of very high concern; vPvB: very persistent and very bioaccumulative.

Further information: This Safety Data Sheet has been prepared in accordance with Annex II of Regulation (EC) No 1907/2006, as amended by Regulation (EU) 2020/878. The information provided is based on the present state of our knowledge and is intended to describe the product with regard to safety requirements. It does not constitute a guarantee of specific product properties.