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: Haemolysis Assay Kit for Biomaterials

Product number: K003 (kit; components listed in Section 3)

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

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 as a whole is not classified. Component K003-10 is classified as follows:

RBS cleaning solution (K003-10): Met. Corr. 1, H290; Skin Corr. 1B, H314; Eye Dam. 1, H318; Aquatic Chronic 3, H412 (classification of the supplier for RBS 35 concentrate, which is supplied undiluted in the kit).

Other components: Not classified according to Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Component K003-10: Hazard pictogram GHS05 (corrosion). Signal word: Danger.

Hazard statement: H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage. H412 Harmful to aquatic life with long lasting effects.

Precautionary statements: P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Hazardous ingredients for labelling: sodium hydroxide, sodium hypochlorite, dodecylbenzenesulphonic acid.

Supplemental information (K003-1, K003-3, K003-11, K003-12): 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.

Other components: No labelling required.

2.3 Other hazards: The Erythrocyte concentrate (K003-1) and the Haemoglobin standard (K003-5) are of human origin. Although each donation has been tested and found negative for anti-HIV-1/2, HBsAg, anti-HCV, Syphilis, HIV1 RNA, HBV DNA and HCV DNA, no test method can completely exclude the presence of infectious agents. Handle as potentially infectious material (biosafety level 2). 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)
K003-1	Erythrocyte concentrate (human erythrocytes in cryopreservative medium), 3 × 3 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208

Code	Component	Hazardous ingredients	Classification (CLP)
K003-3	Dilution buffer III (buffered saline solution), 100 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K003-4	Lysis fluid (aqueous solution), 8 mL	None	Not classified
K003-5	Haemoglobin standard (human), 10 mg/mL, 0.5 mL	None	Not classified
K003-6	Assay buffer (aqueous solution), 10 mL	None	Not classified
K003-7	Reference 1: silicone elastomer (SE), 4 pieces	None (article)	Not applicable
K003-8	Reference 2: nitrile rubber (Buna-N), 4 pieces	None (article)	Not applicable
K003-9	Reference 3: titanium (Ti), 4 pieces	None (article)	Not applicable
K003-10	RBS cleaning solution (RBS 35 concentrate, Carl Roth), 2 mL	Sodium carbonate (CAS 497-19-8) < 5%; tetrapotassium pyrophosphate (CAS 7320-34-5) < 5%; sodium hypochlorite solution (CAS 7681-52-9) < 2.5%; dodecylbenzenesulphonic acid (CAS 27176-87-0) < 2%; sodium hydroxide (CAS 1310-73-2) < 2%	Met. Corr. 1, H290; Skin Corr. 1B, H314; Eye Dam. 1, H318; Aquatic Chronic 3, H412
K003-11	Dilution buffer I (buffered saline solution), 10 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K003-12	Dilution buffer II (buffered saline solution), 10 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208

Only ingredients that must be declared under REACH Annex II, Section 3.2, are listed; concentrations are given as ranges. The reference materials (K003-7 to K003-9) 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. After contact with the RBS cleaning solution (K003-10), seek immediate medical attention (ophthalmologist).

Skin contact: Wash with soap and plenty of water. After contact with material of biological origin, disinfect the affected area. After contact with the RBS cleaning solution, remove contaminated clothing, rinse the skin with plenty of water and seek medical advice.

Ingestion: Rinse mouth with water. Do not induce vomiting. After ingestion of the RBS cleaning solution, give a glass of water to drink if the person is conscious and seek immediate medical attention.

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: RBS cleaning solution (K003-10): severe burns of skin, eyes and mucous membranes; risk of serious eye damage and blindness; if swallowed, risk of perforation of the oesophagus and stomach. Other components: 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, or at least the erythrocytes, between −80 °C and −20 °C, as cold as possible; the shelf life of six months is based on storage at −80 °C. Once thawed, keep the erythrocytes at 2–8 °C and do not refreeze them; the other reagents may be refrozen. RBS cleaning solution: the supplier recommends storage at 15–25 °C in a container that is not sealed gas-tight; keep away from acids and metals. 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). When handling the RBS cleaning solution concentrate: tightly fitting safety goggles and face protection.

Hand protection: Disposable nitrile gloves (EN ISO 374-1). Replace gloves immediately if contaminated or damaged. RBS cleaning solution: nitrile rubber gloves, thickness ≥ 0.3 mm (breakthrough time > 480 min, according to the supplier).

Body protection: Laboratory coat.

Respiratory protection: Not required under normal conditions of use. If aerosols or mist of the RBS cleaning solution are formed: combined filter type ABEK.

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; solid reference materials (K003-7 to K003-9)
Colour	Red (erythrocyte concentrate, haemoglobin); colourless (solutions); references: various
Odour	Odourless or faint characteristic odour
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
Flash point	Not applicable (aqueous solutions)
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
pH	4–10; RBS cleaning solution 12.9–13.3 (20 °C)
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 applicable

9.2 Other information: The erythrocyte suspension and the haemoglobin solution are 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: RBS cleaning solution: violent reaction with strong acids; contact with acids may release chlorine. Corrosive to metals; contact with light metals (e.g. aluminium, zinc) releases hydrogen. Other components: none known.

10.4 Conditions to avoid: Heat. Refreezing of thawed erythrocytes.

10.5 Incompatible materials: Strong oxidising agents. RBS cleaning solution: acids, metals, light metals.

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. RBS cleaning solution (K003-10): causes severe skin burns and serious eye damage (supplier data; classification by the additivity method); not classified for acute toxicity, sensitisation, CMR properties or specific target organ toxicity. Other components: based on the available data, the classification criteria are not met for any 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: Components of human origin 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 kit. RBS cleaning solution (K003-10) is harmful to aquatic life with long lasting effects (Aquatic Chronic 3, H412), mainly because of its sodium hypochlorite content. The other 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 kit, its containers and contaminated materials as biological (potentially infectious) waste, e.g. by autoclaving or incineration. Dispose of unused RBS cleaning solution as hazardous chemical waste (HP 8 corrosive, HP 14 ecotoxic); do not discharge into drains. Follow local and national regulations.

SECTION 14: Transport information

The kit is not classified as dangerous goods, with the exception of the RBS cleaning solution (K003-10):

14.1 UN number or ID number: UN 1824 (RBS cleaning solution K003-10)

14.2 UN proper shipping name: SODIUM HYDROXIDE SOLUTION

14.3 Transport hazard class(es): 8

14.4 Packing group: III

14.5 Environmental hazards: None (not environmentally hazardous according to the dangerous goods regulations)

14.6 Special precautions for user: The quantity of RBS cleaning solution per kit (2 mL) is within the limits for transport as an excepted quantity (code E1). The other components are not dangerous goods. Ship on dry ice. Fragile containers; handle with care. When shipped on dry ice, the outer packaging is additionally 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: H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. H412 Harmful to aquatic life with long lasting effects. 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.