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: CH50 Assay Kit

Product number: K002 (kit; components listed in Section 3)

1.2 Relevant identified uses: Laboratory reagent kit for research use only: determination of classical pathway haemolytic complement activity.

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

The kit as a whole is not classified. The Lysis fluid (K002-3) contains Triton X-100 at or above 0.1% (w/w) and is classified as Endocrine disruptor for the environment, Category 1 (ED ENV 1), EUH430. The other components are not classified as hazardous according to Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Hazard pictograms, signal word, hazard statements: Component K002-3: no hazard pictogram; signal word Danger; EUH430 May cause endocrine disruption in the environment. P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulations. Other components: none.

Supplemental information (K002-2, K002-4): 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 Erythrocyte concentrate (K002-1) consists of sheep (ovine) erythrocytes, obtained from animals that have been inspected and approved for human consumption, sensitised with an anti-sheep erythrocyte antibody of rabbit origin. The References are freeze-dried 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. Handle all components of biological origin as potentially infectious material (biosafety level 2). Some components contain protein of bovine origin. The Lysis fluid (K002-3) contains Triton X-100 above 0.1%, a substance of very high concern with endocrine-disrupting properties for the environment (see Sections 2.1, 3, 12 and 15). No component meets the PBT/vPvB criteria.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Code	Component	Hazardous ingredients	Classification (CLP)
K002-1	Erythrocyte concentrate (sensitised sheep erythrocytes in preservative solution), 1.2 mL	None	Not classified
K002-2	Dilution buffer (buffered saline solution), 100 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K002-3	Lysis fluid, 3.5 mL	Triton X-100 (CAS 9036-19-5) ≥ 0.1 – < 1% (SVHC)	ED ENV 1, EUH430

Code	Component	Hazardous ingredients	Classification (CLP)
K002-4	Stop solution (buffered saline solution), 100 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208
K002-5	Reference 1 (low complement activity), freeze-dried human plasma	None	Not classified
K002-6	Reference 2 (normal complement activity), freeze-dried human plasma	None	Not classified

Only ingredients that must be declared under REACH Annex II, Section 3.2, are listed; concentrations are given as ranges. Triton X-100 (CAS 9036-19-5) is classified by the supplier as Acute Tox. 4 (H302), Skin Irrit. 2 (H315), Eye Dam. 1 (H318), Aquatic Acute 1 (H400; M-factor 10), Aquatic Chronic 1 (H410; M-factor 1) and Endocrine disruptor for the environment, Category 1 (EUH430). At the concentration in the Lysis fluid only the endocrine-disruptor classification applies. 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 cautiously 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 biological 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, in particular the Lysis fluid, 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 4–6 °C. Keep containers tightly closed. Do not freeze the erythrocyte concentrate. 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 (K002-1 to K002-4); freeze-dried powder (K002-5, K002-6)
Colour	Red (erythrocyte concentrate); colourless to pale yellow (other components)
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

Property	Value
pH	6–8
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 references)

9.2 Other information: The erythrocyte suspension (sheep) and the reference plasmas (human) are of biological 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: The Lysis fluid contains Triton X-100, listed because of endocrine-disrupting properties in the environment; no endocrine-disrupting effects on human health are expected at the concentration present.

Other information: Components of biological 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. Triton X-100 is very toxic to aquatic life with long lasting effects (M-factors 10 acute, 1 chronic); at the concentration in the Lysis fluid it does not lead to classification for aquatic toxicity. The other components are not classified as hazardous to the aquatic environment.

12.2 Persistence and degradability: Triton X-100 is not readily biodegradable (supplier data: 22% in 28 days, OECD 301C). The biological components (proteins, cells) are readily biodegradable.

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: The Lysis fluid contains Triton X-100, identified as a substance of very high concern because of endocrine-disrupting properties in the environment (REACH Article 57(f)); the Lysis fluid is classified as ED ENV 1 (EUH430).

12.7 Other adverse effects: Avoid release of the Lysis fluid to the environment.

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 and store at 4–6 °C with cooling elements. Fragile containers; handle with care.

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.
- Animal by-products: HaemoScan is registered with the Netherlands Food and Consumer Product Safety Authority (NVWA) for the manufacture of category 3 laboratory reagents (Regulation (EC) No 1069/2009).
- REACH Candidate List / Annex XIV: Triton X-100 (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated) is included in Annex XIV (entry 42; sunset date 04-01-2021). Use in scientific research and development, including routine analytics, is exempt from authorisation (REACH Article 56(3)), as also stated by the supplier.

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. EUH430 May cause endocrine disruption in the environment. (Triton X-100 as supplied: H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.)

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; ED ENV: endocrine disruptor for the environment; 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.