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: N-Acetyl-β-D-glucosaminidase (NAG) Assay Kit

Product number: K006 (kit; components listed in Section 3)

1.2 Relevant identified uses: Laboratory reagent kit for research use only: determination of N-acetyl-β-D-glucosaminidase 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

Kit: The kit as a whole is not classified. Component K006-2 is classified as follows:

Stop solution (K006-2): Eye Irrit. 2, H319

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

2.2 Label elements

Component K006-2: Hazard pictogram GHS07 (exclamation mark). Signal word: Warning.

Hazard statement: H319 Causes serious eye irritation.

Precautionary statements: P264 Wash hands thoroughly after handling. P280 Wear eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.

Supplemental information (K006-4): 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.

Other components: No labelling required.

2.3 Other hazards: The Controls (K006-5, K006-6) are prepared from human urine of a healthy volunteer. The urine has not been tested for pathogens; handle the controls as potentially infectious material (biosafety level 2). The NAG standard (K006-3) contains an enzyme of plant 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)
K006-1	NAG substrate (chromogenic substrate in acidic buffer), 22 mL	None	Not classified
K006-2	Stop solution (alkaline solution), 22 mL	Sodium carbonate (CAS 497-19-8) ≥ 5 – < 10%	Eye Irrit. 2, H319
K006-3	NAG standard (25 U/L), 500 µL	None	Not classified
K006-4	Dilution buffer (protein-containing saline solution), 4 mL	Isothiazolinone preservative (CMIT/MIT, CAS 55965-84-9) < 0.0015%	Not classified; EUH208

Code	Component	Hazardous ingredients	Classification (CLP)
K006-5	Control 1 (normal), human urine, 500 µL	None	Not classified
K006-6	Control 2 (high), human urine with added NAG, 500 µL	None	Not classified

Only ingredients that must be declared under REACH Annex II, Section 3.2, are listed; concentrations are given as ranges. 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: Stop solution (K006-2): eye irritation (redness, pain). Other components: no specific symptoms known; the controls may contain infectious agents (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 or colder, as cold as possible; the shelf life of one year is based on storage at −20 °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
Colour	Colourless to pale yellow
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	Substrate approx. 4.5; Stop solution approx. 11.6; Dilution buffer approx. 7
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)

Property	Value
Relative vapour density	Not applicable
Particle characteristics	Not applicable (liquids)

9.2 Other information: After the Stop solution is added, a yellow colour develops. The controls 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: 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. Stop solution: acids (release of carbon dioxide).

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. Stop solution (K006-2): causes serious eye irritation (alkaline solution). 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: The controls 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.

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: H319 Causes serious eye irritation. 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.