

Path-Chek Hygiene Protein Swabs

(Cat. nr. PC-006)

SECTION 1: Identification of the substance/preparation and of the Company/Undertaking

1.1. Product identifiers

Product name

Path-Chek Hygiene Protein Swabs

Cat. Nr.

PC-006

1.2. Product Use

Swab for detection of protein residues on surfaces.

1.3. Company/Undertaking identification

Gold Standard Diagnostics Budapest Kft.

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1.4. Emergency telephone

Please, contact your local Poison Centre.

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Ethanol

Flammable liquids, Cat.2 H225

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:

Ethanol

F, Highly flammable

R11: Highly flammable

S7-S16 Keep container tightly closed. Keep away from sources of ignition –

No smoking

2.2. Labelling according to Regulation (EC) No 1272/2008:

The substance is classified as flammable.



Signal word: Danger

H-statements

H225 Highly flammable liquid and vapour.

P-statements

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P241 Use explosion-proof electrical, ventilating and lighting equipment.
P280 Wear protective gloves and eye protection/face protection.
P233 Keep container tightly closed.
P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P370 + P378 In case of fire: Use suitable extinguishing medium for extinction.

SECTION 3: Composition/information on ingredients

Component	Hazardous substance	Concentration	Component classification	CAS No.	EC No.
Swabs	Absolute Ethanol	30-37%	not dangerous	64-17-5	200-578-6

SECTION 4: First Aid Measures

Eye contact – Wash out eyes with plenty of water. Seek medical advice.
Skin contact – Remove any contaminated clothing and wash immediately with plenty of water.
Ingestion – If chemical has been swallowed, give about 250mL water to dilute it in stomach. Do not induce vomiting. If chemical is confined to mouth, wash out with plenty of water. Do not swallow mouthwash. Seek medical advice.
Inhalation- Supply fresh air. Seek immediate medical advice.
Equipment to be available at the workplace for specific and immediate treatment: Eye –washing and skin-washing facilities

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Suitable extinguishing agents: CO₂, water spray, dry chemical, alcohol resistant form.

5.2. Special hazards arising from the mixture

Combustible

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3. Advice for firefighters

Protective equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Apply cooling water to sides of Containers that are exposed to flames. Combat fire out of sheltered position.

5.4. Further information

None.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid substance contact. Avoid inhalation of vapours. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures.

6.2. Environmental precautions

Dispose of according to any local, national or regional regulations

6.3. Methods and materials for containment and cleaning up

Wear personal protective equipment. Ventilate closed spaces before entering. Eliminate all sources of ignition. Absorb spill with inert material (e.g. dry sand or earth), then place in a chemical waste container.

6.4. Further information

None.

SECTION 7: Handling and Storage

7.1. Handling

Do not breathe vapour. Wash face and hands after handling material.

7.2. Storage

Store at 4-25°C away from direct sunlight. Under these conditions swabs will retain their activity until the expiry date shown on the label on outer carton.

7.3. Specific end uses

None.

SECTION 8: Exposure Controls/Personal Protection

8.1. Exposure Limit Values

Ethanol absolute:

OSHA REL: air TWA 1000ppm ACGIH TLV(s): TWA 1000ppm

Glycerin:

OSHA REL: air TWA 15mg/m³ ACGIH TLV(s): TWA 10mg/ m³

8.2. Exposure controls

8.2.1. Occupational

Respiratory	Respiratory protection is not required under normal and intended conditions of use.
Hands	Impermeable protective gloves.
Eyes	Safety glasses with shields recommended.
Body	Laboratory coat or similar protective garment.

SECTION 9: Physical and Chemical Properties

Yellowish liquid impregnated into swab

Alcoholic small

pH approximately 2.5 (20 degrees C)

Boiling Point: No data

Melting Point: No data

Flash Point: No data

Ignition Temperature: No data

Explosion Limits: No data

Vapour Pressure: No data

Density: No data

Vapour Pressure: No data

Solubility: Readily soluble in water and ethanol

SECTION 10: Stability and reactivity

10.1. Stability

Stable under recommended storage conditions. Do not use after stated expiry date. Store at 4-25 °C.

10.2. Materials / Conditions to avoid

Carbon oxides (CO and CO₂) products

Conditions to avoid: Avoid contact with heat, sunlight, spark, flame and ignition sources.

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

Ethanol:

After ingestion and inhalation: inebriation, headache, ataxia, coma

After eye contact; local irritation symptoms

Oral LD50 (rat) 7060mg/kg

LC50 (inhalation, rat) 20,000ppm/10 hours

SECTION 12: Ecological Information

- Persistence and degradability: The following applies to ethanol in general: biodegradable. When used properly, no impairments in the function of waste water treatment plants are to be expected. Fish toxicity; fish LC50:>10,000mg/L; Daphnia Toxicity Daphnia EC0: >7800mg/L
- Bio accumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- Results of PBT and vPvB assessment
 - PBT: Not applicable.
 - vPvB: Not applicable.
- Other adverse effects :No further relevant information available

SECTION 13: Disposal Considerations

Dispose of according to any local, national or regional regulations.

SECTION 14: Transport Information

14.1. UN number

UN3175

14.2. UN proper shipping name

Solids containing Inflammable liquid, 4.1

14.3. Transport hazard class(es)

4.1

14.4. Packing group

II.

But special provision 216 (IATA A46) applies to this product – Sealed packets and articles containing less than 10mL of a packing group II (ethanol in this case) flammable liquid absorbed onto a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.

14.5. Environmental hazards

Not regulated.

14.6. Special precautions for user

Not regulated.

SECTION 15: Regulatory Information

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

Health, safety or environmental information is not required on the label (according to Regulation (EC) No 1272/2008).

SECTION 16: Other information

16.1. Recommended restrictions on use:

This product is intended to be used for laboratory use only by technical staff trained in microbiological techniques. Classification and labelling have been performed according to CLP Regulations.

Read the Instructions for Use for further information on limitations of use.

16.2. Sources of information used to compile this sheet

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH): Article 31: Requirements for safety data sheets, and Annex II: Guide to the compilation of safety data sheets, OJL, 136, 29.5.2007, pp 35-36 and pp 84-89.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (in short CLP).

Commission Decision 2000/532/EC establishing a list of wastes pursuant to Article 1 (a) of Directive 75/442/EEC on Waste and Article 1 (4) of Directive 91/689/EEC on Hazardous Waste. CONSLEG: 2000D0532-01/01/2002, Office for Official Publications of the European Communities.

Approved Supply List (8th edition), Information provided for the classification and labelling of substances and preparations for supply, United Kingdom Health and Safety Commission, 2005 (based on Annex I of 67/548/EEC).

Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices, Annex I, Essential Requirements, OJ L, 331, 7.12.98, p 20.

List of approved workplace exposure limits, Table 1 of EH40/2005, United Kingdom Health and Safety Commission, 2ND edition published 2011, implementing the European Commission's Indicative Occupational Exposure Limit Values Directive 2009/161/EU.

16.3. Changes from previous version

The Ownership of the documents has been changed. The legal Manufacturer is Gold Standard Diagnostics Budapest Kft. (Chapter 1.3).

The above information is based on data available and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determinations of the effects, properties and protections which pertain to their particular conditions.

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