



Safety Data Sheet

In compliance with (EC) 1272/2008 (CLP)

Date of issue: 14.03.2016

1. IDENTIFICATION

Product name:	CalproSmart Office™ rapid test for measurement of calprotectin levels in faecal samples of patients at doctors' offices.
Product classification:	In vitro diagnostic medical device
Catalogue number:	CAL220
Intended use:	The CalproSmart Office™ test is a method for the determination of Calprotectin levels in human stool samples in combination with the dedicated CalproSmart™ smartphone application. The test is intended as a diagnostic tool at doctors' offices to differentiate between patients with inflammatory bowel diseases (IBD) or Irritable Bowel Syndrome (IBS). It is also a tool for measuring the effect of treatment of IBD-patients, identify non-responders and for predicting relapses. The test is for in vitro use.
Manufacturer:	Calpro AS Arnstein Arnebergsvei 30 1366 Lysaker Norway Office Phone: +47 40 00 42 79 E-mail: mail@calpro.no

2. HAZARD(S) IDENTIFICATION

Classification

The product is **not classified as hazardous** according to the European Regulation 1272/2008/EC.

Human health hazards: No specific hazards.

Labelling

The product does not require labeling, pictograms, signal words or hazard statements according to regulation 1272/2008/EC.

Additional information

See Section 3.

3. COMPOSITION / IDENTIFICATION OF INGREDIENTS

No	Component name	Hazard	Classification (pure form) according to Regulation 1272/2008 (EG)		Concentration
			Hazard code	Hazard category	
1	Fecal extraction buffer	Kathon CG ¹⁾	H301 H311 H314 H317 H331 H400 H410	Acute toxicity, oral, Category 3 Acute toxicity, dermal, Category 3 Skin corrosion/irritation, Category 1A, B, C Sensitisation, Skin, Category 1 Acute toxicity, inhalation, Category 3 Aquatic Acute toxicity, Category 1 Aquatic Long-term toxicity, Category 1	0.1%
		Sodium azide ²⁾	H300 H400 H410	Acute toxicity, oral, Category 2 Aquatic Acute toxicity, Category 1 Aquatic Long-term toxicity, Category 1	0.09%
2	Plastic device for sampling and extraction	N/A	N/A	N/A	N/A
3	Disposable paper samplers for collection of stool samples	N/A	N/A	N/A	N/A
4	Nitrile gloves	N/A	N/A	N/A	N/A
5	Disposable lateral flow rapid test cassettes	N/A	N/A	N/A	N/A
6	Rectangular plastic support frame with an opening for placement of the rapid test cartridges	N/A	N/A	N/A	N/A

¹⁾ Kathon CG: Hazardous components are 5-chloro-2-methyl-2H-isothiazol-3-one (CAS-NO. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H-isothiazol-3-one (CAS-NO. 2682-20-4, EC-No. 220-239-6).

²⁾ Sodium azide: (CAS No. 26628-22-8, EC-No. 247-852-1, Index-No. 011-004-00-7)

For precautionary statements (P-statements) related to pure form of hazardous ingredients, see section 16.

4. FIRST-AID MEASURES

Most important symptoms and effects, both acute and delayed:

No further relevant information available

Description of first aid measures:

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash off with plenty of water. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. Seek medical treatment.

After swallowing: Rinse out mouth. If symptoms persist, consult a doctor.

Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Carbon dioxide, dry chemical powder or appropriate foam.

Special fire-fighting procedures: Wear self-contained breathing for firefighting if necessary.

Unusual fire and explosions hazards referred to:

- a) **Azide:** Sodium oxides.
- b) **Kathon:** Carbon oxides, nitrogen oxides (NO_x), Sulphur oxides, Hydrogen chloride gas, Magnesium oxide.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up: Adsorb on filter paper or use sand or other inert material (vermiculite). After recovering, wash contaminated areas and ventilate. Dispose according to section 13. Azide may react with lead and copper, to form explosive metal azides – see section 10. If the product enters the drain, flush immediately with large amounts of water to avoid azide accumulation.

7. HANDLING AND STORAGE

Precautions for safe handling: Wear protective gloves by prolonged exposure. Do not eat, drink or smoke when using this product. Handle device after fecal sampling as potentially biohazard material.

Precautions for safe storage: No special requirements

Storage temperature: Store extraction devices and lateral flow assay cassettes at 2 – 8° C in original container.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Referred to extraction solution:

Permissible Exposure Limits (PELs): No further relevant information available.

Threshold Limit Values (TLVs): No further relevant information available.

Appropriate engineering controls: No further relevant information available.

Personal protective equipment (PPE):

Inhalation: Respiratory equipment is normally not required.

Skin: Wear protective gloves of nitrile or butyl rubber.

Eyes: Wear safety goggles when risk of eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

The product appears as a prefilled plastic device for sampling and extraction of fecal samples. The device is filled with 5.0 mL extraction buffer. The extraction buffer is a transparent liquid with pH: 7.8-8.2

10. STABILITY AND REACTIVITY

Referred to extraction solution:

Stability: Stable at storage conditions (2-8°C; 35.6-46.4°F)

Incompatibilities referred to:

Azide: Halogenated hydrocarbon. Metals, Acids, Acid chlorides, Hydrazine, Dimethyl sulphate, Inorganic and acid chlorides.

Kathon: Strong oxidizing agents, Strong reducing agents, Amines, Thiols.

Hazardous combustion or decomposition products: No data available.

In the event of fire: See section 5.

Hazardous polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute toxicity:

LD/LC50 values relevant for classification:

Quantitative data on the toxicological effect of this product are not available.

Primary irritant effect:

On the skin: No further relevant information available.

On the eye: No further relevant information available.

After inhalation: No further relevant information available.

Sensitization: No further relevant information available.

Additional toxicological information:

The product is **not classified as hazardous** according to the European Regulation 1272/2008/EC because the concentrations of hazardous substances are below the classification limits ($\leq 0.1\%$). When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

For toxicological information on pure hazardous components see section 16.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bio accumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB assessment referred to:

Azide: This substance/mixture contains no components considered to be persistent, bio accumulative and toxic (PBT), or very persistent and very bio accumulative (vPvB) at levels of 0.1% or higher.

Kathon: PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

Other adverse effects referred to:

Azide: Very toxic to aquatic life with long lasting effects.

Kathon: Toxic to aquatic life.

No further relevant information available.

13. DISPOSAL CONSIDERATION

The Easy Sampler part of the system is biodegradable, and should be flushed down the toilet after use. Collect any spillage. Do not let product enter drains. Discharge into the environment must be avoided. Extraction device and lateral flow assay cassettes after use should be treated in accordance with disposal practices employed for infectious waste (special waste).

Dispose of contents/container to be burned in a chemical incinerator equipped with an afterburner and scrubber.

14. TRANSPORT INFORMATION

This product is not subject to official transport regulations.

15. REGULATORY INFORMATION

1272/2008/EC Classification, labeling and packaging regulation (CLP, globally harmonized system GHS)

This product is not classified according to the EU regulations 1272/2008. No labeling requirement.

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

No data available

Chemical Safety Assessment: For this product a chemical safety assessment has not been carried out.

16. OTHER INFORMATION

DISCLAIMER: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only.

It should not therefore be construed as guaranteeing any specific property of the product. Please, read well instruction for use and warnings.

Toxicological information on pure hazardous components in fecal extraction buffer:

Referred to Kathon CG components in pure form (source of information Sigma-Aldrich):

Acute toxicity

LD50 Oral - rat - female - 2.630 mg/kg

LD50 Oral - rat - male - 3.350 mg/kg

No data available

Skin corrosion/irritation

Skin - rabbit

Result: Corrosive

Serious eye damage/eye irritation

Eyes - rabbit

Result: Corrosive

Respiratory or skin sensitization

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: 2A - Group 2A: Probably carcinogenic to humans (Magnesium nitrate hexahydrate)

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

Referred to sodium azide in pure form (source of information Sigma-Aldrich):**Acute toxicity**

LD50 Oral - Rabbit - 10 mg/kg

LC50 Inhalation - Rat - 37 mg/m³

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Other.

Behavioral: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Structural or functional change in trachea or bronchi.

LD50 Dermal - Rabbit - 20 mg/kg

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: VY8050000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Nausea, Headache, Vomiting, Laboratory experiments on animals have shown sodium azide to cause a profound hypotensive effect, demyelination of myelinated nerve fibers in the central nervous system, testicular damage, blindness, attacks of rigidity, and hepatic and cerebral effects. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Precautionary statements (P-statements) related to pure form of hazardous ingredients:**Related to H300: Acute toxicity, oral, Category 1, 2**

P264: Wash ... thoroughly after handling

P270: Do not eat, drink or smoke when using this product

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell

P321: Specific treatment (see ... on this label)

P330: Rinse mouth

P405: Store locked up

P501: Dispose of contents/container to ...

Related to H301: Acute toxicity, oral, Category 3

P264: Wash ... thoroughly after handling

P270: Do not eat, drink or smoke when using this product

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell

P321: Specific treatment (see ... on this label)

P330: Rinse mouth

P405: Store locked up

P501: Dispose of contents/container to ...

Related to H311: Acute toxicity, dermal, Category 3

P280: Wear protective gloves/protective clothing/eye protection/face protection

P302+P352: IF ON SKIN: Wash with plenty of soap and water

P312: Call a POISON CENTER or doctor/physician if you feel unwell

P322: Specific measures (see ... on this label)

P361: Remove/Take off immediately all contaminated clothing

P363: Wash contaminated clothing before reuse

P405: Store locked up

P501: Dispose of contents/container to ...

Related to H314: Skin corrosion/irritation, Category 1A, B, C

P260: Do not breathe dust/fume/gas/mist/vapors/spray

P264: Wash ... thoroughly after handling

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): Remove/Take off immediately all contaminated clothing. Rinse skin

P363: Wash contaminated clothing before reuse

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P310: Immediately call a POISON CENTER or doctor/physician

P321: Specific treatment (see ... on this label)

P305+ P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P405: Store locked up

P501: Dispose of contents/container to ...

Related to H317: Sensitisation, Skin, Category 1

P261: Avoid breathing dust/fume/gas/mist/vapors/spray

P272: Contaminated work clothing should not be allowed out of the workplace

P280: Wear protective gloves/protective clothing/eye protection/face protection

P302+P352: IF ON SKIN: Wash with plenty of soap and water

P333+P313: If skin irritation or rash occurs: Get medical advice/attention

P321: Specific treatment (see ... on this label)

P363: Wash contaminated clothing before reuse

P501: Dispose of contents/container to ...

Related to H331: Acute toxicity, inhalation, Category 3

P261: Avoid breathing dust/fume/gas/mist/vapors/spray

P271: Use only outdoors or in a well-ventilated area
P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P311: Call a POISON CENTER or doctor/physician
P321: Specific treatment (see ... on this label)
P403+P233: Store in a well-ventilated place. Keep container tightly closed
P405: Store locked up
P501: Dispose of contents/container to ...

Related to H400: Hazardous to the aquatic environment, acute hazard, Category 1

P273: Avoid release to the environment
P391: Collect spillage
P501: Dispose of contents/container to ...

Related to H410: Hazardous to the aquatic environment, long-term hazard, Category 1

P273: Avoid release to the environment
P391: Collect spillage

History:

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This safety sheet has been drafted according to the directives issued by the council and the commission of the European communities.

The purpose of the safety sheet is to ensure correct and safe use, storage, shipment and disposal of the preparation. All included information is based on our knowledge of the preparation at the date of issue of this sheet. It does not represent a guarantee of the properties of the product.

For further information about the preparation please contact Calpro AS at mail@calpro.no or www.calpro.com.