

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 02.06.2023

Version number 2 (replaces version 1)

Revision: 02.06.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name:** **foodproof®** and **microproof® LyoKits**

· **Product variants:**

- KIT230020 / foodproof® E. coli and Shigella Detection LyoKit - LP (Ref. F 602 09-1)
- KIT230021 / foodproof® E. coli and Shigella Detection LyoKit - RP (Ref. F 602 09-2)
- KIT230329 / foodproof® E. coli and Shigella Detection LyoKit - DP (Ref. F 602 09-3)
- KIT230077 / foodproof® STEC Screening LyoKit - LP (Ref. R 602 11-1)
- KIT230078 / foodproof® STEC Screening LyoKit - RP (Ref. R 602 11-2)
- KIT230079 / foodproof® STEC Identification LyoKit - LP (Ref. R 602 12-1)
- KIT230080 / foodproof® STEC Identification LyoKit - RP (Ref. R 602 12-2)
- KIT230119 / microproof® Legionella Quantification LyoKit - LP (Ref. R 602 45-1)
- KIT230120 / microproof® Legionella Quantification LyoKit - RP (Ref. R 602 45-2)
- KIT230145 / foodproof® Aspergillus Detection LyoKit - LP (Ref. R 602 72-1)
- KIT230146 / foodproof® Aspergillus Detection LyoKit - RP (Ref. R 602 72-2)
- KIT230147 / foodproof® Aspergillus Detection LyoKit - DP (Ref. R 602 72-3)
- KIT230032 / foodproof® Animal Detection 2 LyoKit (Chicken, Turkey, Poultry) - LP (Ref. F 602 79-1)
- KIT230033 / foodproof® Animal Detection 2 LyoKit (Chicken, Turkey, Poultry) - RP (Ref. F 602 79-2)
- KIT230115 / foodproof® Porcine Detection LyoKit - LP (Ref. R 602 43-1)
- KIT230116 / foodproof® Porcine Detection LyoKit - RP (Ref. R 602 43-2)
- KIT230127 / foodproof® Animal Detection 1 LyoKit - LP (Ref. R 602 49-1)
- KIT230128 / foodproof® Animal Detection 1 LyoKit - RP (Ref. R 602 49-2)

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the mixture**

PCR-Kit for the detection of certain DNA. Target DNA as specified on separate enclosure.

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Hygiena Diagnostics GmbH
Hermannswerder 17
14473 Potsdam
GERMANY
Phone: +49 (0) 331-23 00 200
www.hygiena.com

BIOTECON Diagnostics GmbH
Hermannswerder 17
14473 Potsdam
GERMANY
Phone: +49 (0) 331-23 00 200
www.bc-diagnostics.com

· **Informing department:**

Phone: +49 (0) 331-23 00 200
Fax: +49 (0) 331-23 00 299

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· **1.4 Emergency telephone number:**

Phone: +49 (0) 331-23 00 200

Office hours: 09:30 - 16:00

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.
- **Additional information:** Set composed of separate, different vials.

· **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

- **Additional information:**

Safety data sheet available on request.

- **Labelling of packages where the contents do not exceed 125 ml**

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

· **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

- **Description:**

PCR-Kit for the detection of certain DNA. Target DNA as specified on separate enclosure.

- **Dangerous components:**

68131-40-8	Alcohols, C11-15-secondary, ethoxylated	< 2.5%
	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Aquatic Chronic 3, H412	

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

- **General information** Remove contaminated clothing immediately.
- **After inhalation** Supply fresh air; consult doctor in case of symptoms.
- **After skin contact**
Wash with water and soap.
If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents**
The product itself does not burn.
Use fire fighting measures that suit the environment.
 - **For safety reasons unsuitable extinguishing agents** None known.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Inhalation of combustion gases may cause serious health hazards.
- **5.3 Advice for firefighters**
 - **Protective equipment:** Wear self-contained breathing apparatus.
 - **Additional information**
Collect contaminated fire fighting water separately. It must not enter drains. Provide sufficient fire fighting water retention.
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Avoid contact with the product.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or water bodies.
Do not allow to enter drainage system, surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Send for recovery or disposal in suitable containers.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Store in cool, dry place in tightly closed containers.
Keep away from heat and direct sunlight.
Avoid contact with eyes and skin.
Prevent formation of dust.
 - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** Store only in the original container.
 - **Information about storage in one common storage facility:**
Keep away from strong oxidizing, alkalis and acidic materials.
 - **Further information about storage conditions:**
Store in the dark.
Protect from the effects of light.
 - **Recommended storage temperature:** < 25°C.

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- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· **Components with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- **Additional information:** The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures**

Wash hands during breaks and at the end of the work.

- **Breathing equipment:** Not required when used as intended.

· **Hand protection**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

In case of a layer thickness of 0.11 mm the penetration time is longer than 480 minutes.

· **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Nitrile rubber, NBR

· **Eye/face protection**



Tightly sealed safety glasses.

- **Body protection:** Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· **General Information**

· **Physical state**

Solid

· **Colour:**

Colourless

· **Odour:**

Light

· **Odour threshold:**

Not determined.

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<ul style="list-style-type: none"> · Melting point/freezing point: · Boiling point or initial boiling point and boiling range · Flammability · Lower and upper explosion limit <ul style="list-style-type: none"> · Lower: · Upper: · Flash point: · Decomposition temperature: · SADT · pH · Viscosity: <ul style="list-style-type: none"> · Kinematic viscosity · dynamic: · Solubility <ul style="list-style-type: none"> · Water: · Vapour pressure at 20 °C: · Density and/or relative density <ul style="list-style-type: none"> · Density · Relative density · Vapour density · Particle characteristics <p>See section 3.</p>	<p>Not determined</p> <p>100 °C (7732-18-5 water, distilled, conductivity or of similar purity)</p> <p>Not determined.</p> <p>Not determined.</p> <p>Not determined.</p> <p>Not applicable</p> <p>Not determined.</p> <p>Not determined.</p> <p>Not applicable.</p> <p>Not applicable.</p> <p>Soluble</p> <p>23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)</p> <p>Not determined</p> <p>Not determined.</p> <p>Not applicable.</p>
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· 9.2 Other information

<ul style="list-style-type: none"> · Appearance: · Form: · Important information on protection of health and environment, and on safety. · Self-inflammability: · Explosive properties: · Change in condition · Evaporation rate 	<p>Fluid</p> <p>Product is not selfigniting.</p> <p>Product is not explosive.</p> <p>Not applicable.</p>
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· Information with regard to physical hazard classes

<ul style="list-style-type: none"> · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids · Pyrophoric solids · Self-heating substances and mixtures · Substances and mixtures, which emit flammable gases in contact with water · Oxidising liquids · Oxidising solids · Organic peroxides · Corrosive to metals 	<p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p>
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· **Desensitised explosives** Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
None in case of intended use and storage in compliance with instructions.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
 - **Other information:** There are no data available about the preparation.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
 - **Additional ecological information:**
 - **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

The waste code numbers mentioned are recommendations based on the probable use of the product.

· **European waste catalogue**

07 00 00	WASTES FROM ORGANIC CHEMICAL PROCESSES
07 07 00	wastes from the MFSU of fine chemicals and chemical products not otherwise specified
07 07 01*	aqueous washing liquids and mother liquors
18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 02 00	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 05*	chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**

· **Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings can be used for recycling.

Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

· **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

· 14.1 UN number or ID number

· **ADR/RID, IMDG, IATA** Void

· 14.2 UN proper shipping name

· **ADR/RID, IMDG, IATA** Void

· 14.3 Transport hazard class(es)

· **ADR/RID, ADN, IMDG, IATA**
· **Class** Void

· 14.4 Packing group

· **ADR/RID, IMDG, IATA** Void

· 14.5 Environmental hazards:

· **Marine pollutant:** No

· 14.6 Special precautions for user

Not applicable.

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

· **Transport/Additional information:**

Not dangerous according to the above specifications.

· **UN "Model Regulation":**

Void

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SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 65

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· **Substances of very high concern (SVHC) according to REACH, Article 57**

None of the ingredients is contained.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This data sheet considers labelling requirements of Regulation (EU) 2022/692 adapting Regulation (EC) No 1272/2008 (18th ATP of the CLP Regulation).

This safety data sheet meets the requirements of Regulation (EU) 2015/830 and 2020/878 amending Annex II of Regulation (EC) 1907/2006.

· **Relevant phrases**

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H412 Harmful to aquatic life with long lasting effects.

· **Department issuing data specification sheet:**



This Safety Data Sheet has been drawn up in cooperation with:

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· **Date of previous version:** 30.05.2023

· **Version number of previous version:** 1

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

• *** Data compared to the previous version altered.**

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