

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

Printing date 31.05.2023

Version number 1

Revision: 31.05.2023

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

· **1.1 Product identifier**

· **Trade name:** foodproof Detection and Quantification PCR Kits

· **Product variants:**

- KIT230018 / foodproof® Yersinia enterocolitica and pseudotuberculosis Detection Kit (Ref. F 302 53)
- KIT230034 / foodproof® E. coli and Shigella Detection Kit (Ref. R 300 09)
- KIT230035 / foodproof® E. coli O157 Detection Kit - Hybridization Probes - (Ref. R 300 10)
- KIT230036 / foodproof® Listeria monocytogenes Detection Kit (Ref. R 300 23)
- KIT230040 / foodproof® Brucella Detection Kit (Ref. R 302 04)
- KIT230041 / foodproof® Campylobacter Quantification Kit (Ref. R 302 05)
- KIT230042 / foodproof® E. coli O157 Detection Kit (Ref. R 302 10)
- KIT230043 / foodproof® Enterobacteriaceae plus Cronobacter Detection Kit (Ref. R 302 15.1)
- KIT230044 / foodproof® GMO Bt176 Maize Quantification Kit (Ref. R 302 16)
- KIT230045 / foodproof® GMO Screening Kit (35S, NOS, bar, FMV) (Ref. R 302 17)
- KIT230046 / foodproof® GMO RR Soya Quantification Kit (Ref. R 302 19)
- KIT230047 / foodproof® Listeria Genus Detection Kit (Ref. R 302 20)
- KIT230048 / foodproof® Listeria monocytogenes Detection Kit (Ref. R 302 23)
- KIT230049 / foodproof® Salmonella Detection Kit (Ref. R 302 27)
- KIT230050 / foodproof® Salmonella Detection Kit (Ref. R 302 27 L)
- KIT230051 / foodproof® Alicyclobacillus Detection Kit (Ref. R 302 28)
- KIT230052 / foodproof® GMO 35S Maize Quantification Kit (Ref. R 302 29)
- KIT230066 / foodproof® Beer Screening Kit - Hybridization Probes - (Ref. R 310 02)
- KIT230067 / foodproof® Campylobacter Detection Kit - Hybridization Probes - (Ref. R 310 05)
- KIT230068 / foodproof® Enterobacteriaceae plus Cronobacter Detection Kit (Ref. R 310 15.1)
- KIT230069 / foodproof® Enterobacteriaceae plus Cronobacter Detection Kit (Ref. R 310 15.1 L)
- KIT230070 / foodproof® Salmonella Detection Kit - Hybridization Probes - (Ref. R 310 27)

· **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.

· **2.2 Label elements**

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

· **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.

· **Determination of endocrine-disrupting properties**

The product does not contain substances with endocrine disrupting properties.

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:**

CAS: 56-81-5	glycerol	25 - 50%
EINECS: 200-289-5	substance with a Community workplace exposure limit	
Reg.nr.: 01-2119471987-18-X		

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**

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact**

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

· **After swallowing** Do not induce vomiting; instantly call for medical help.

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

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents**
Extinguishing powder, foam or water jet. Fight larger fires with water jet or alcohol-resistant foam.
 - **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.
- **5.3 Advice for firefighters**
 - **Protective equipment:** Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Observe information for safe handling (item 7) and personal protective equipment (item 8).
- **6.2 Environmental precautions:**
Inform respective authorities in case product reaches water or sewage system.
Do not allow to enter drainage system, surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Send for recovery or disposal in suitable containers.
Absorb liquid components with liquid-binding material.
Complete cleaning with water.
- **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.
 - **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.
Prevent any penetration into the ground.
 - **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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
 - **Components with limit values that require monitoring at the workplace:**
WEL: workplace exposure limit
OEL: Occupational Exposure Limit

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56-81-5 glycerol

WEL (Great Britain) Long-term value: 10 mg/m³

- **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

The usual precautionary measures should be adhered to general rules for handling chemicals.

- **Breathing equipment:** Not necessary if room is well-ventilated.

- **Hand protection** Use gloves of stable material (i.e. nitril rubber).

· 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.

· 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** Safety glasses recommended during refilling.

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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Colour:	Colourless
· Odour:	odourless
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	> 100 °C
· Flash point:	Not applicable
· SADT	
· pH	Not determined.
· Solubility	
· Water:	Fully miscible
· Density and/or relative density	
· Density	Not determined

· 9.2 Other information

· Appearance:

- **Form:** Liquid

· Important information on protection of health and environment, and on safety.

- **Self-inflammability:** Product is not selfigniting.

- **Explosive properties:** Product is not explosive.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void

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· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· 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.

· **LD/LC50 values that are relevant for classification:**

56-81-5 glycerol

Oral	LD50	27,200 mg/kg (rat)
Dermal	LD50	56,750 mg/kg (guinea pig)
Inhalative	LC50	> 11 mg/l/1h (rat)

- **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.

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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

56-81-5 glycerol

EC50 (static)	1,955 mg/l/48h (Daphnia magna)
IC5	> 10,000 mg/l/7d (Scenedesmus quadricauda)
EC5	> 10,000 mg/l/16h (Pseudomonas putida)
EC5	3,200 mg/l/72h (Entosiphon sulcatum)
LC50 (static)	54,000 mg/l/96h (Oncorhynchus mykiss)

· **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.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· **Recommendation** Proceed according to local, official regulations.

· 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 08*	other still bottoms and reaction residues

· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations.

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

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

SECTION 14: Transport information

· 14.1 UN number or ID number

· **ADR/RID, ADN, IMDG, IATA** Void

· 14.2 UN proper shipping name

· **ADR/RID, ADN, IMDG, IATA** Void

· 14.3 Transport hazard class(es)

· **ADR/RID, ADN, IMDG, IATA**

· **Class** Void

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· 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

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.

· **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.

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· **Department issuing data specification sheet:**

► **DEKRA** This Safety Data Sheet has been drawn up in cooperation with:
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· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative

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