

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

Printing date 14.02.2023

Version number 1

Revision: 14.02.2023

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

· **1.1 Product identifier**

· **Trade name:** foodproof Allergen Detection Kits

· **Product variants:**

- KIT230057 - foodproof® Celery Detection Kit (Ref. R 302 60)
- KIT230058 - foodproof® Soya Detection Kit (Ref. R 302 61)
- KIT230059 - foodproof® Hazelnut Detection Kit (Ref. R 302 62)
- KIT230060 - foodproof® Peanut Detection Kit (Ref. R 302 63)
- KIT230061 - foodproof® Gluten Detection Kit (Ref. R 302 64)

· **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 using real-time-PCR. Target DNA as specified on separate enclosure.

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

· **Manufacturer/Supplier:**

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

BIOTECON Diagnostics GmbH
Hermannswerder Haus 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

· **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.

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 · **vPvB:** Not applicable.

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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: 57-50-1	sucrose, pure	2.5 - 10%
EINECS: 200-334-9	substance with a Community workplace exposure limit	

 · **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** If skin irritation continues, consult a doctor.

 · **After eye contact** Call a doctor immediately.

 · **After swallowing** In case of persistent symptoms consult doctor.

· 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.

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.

· 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

Not required.

· 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.

· 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.

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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.

- **Recommended storage temperature:** approx. 2°C to 8°C

- **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

57-50-1 sucrose, pure

WEL (Great Britain)	Short-term value: 20 mg/m ³
	Long-term value: 10 mg/m ³

- **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.

- **Hand protection**

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

- 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.

- **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** Not required.

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

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

- | | |
|---|-------------------------------|
| · Colour: | Different according to colour |
| · Odour: | odourless |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Not determined |
| · Boiling point or initial boiling point and boiling range | Not determined |
| · Flammability | Not determined. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable |
| · Decomposition temperature: | Not determined. |
| · SADT | |
| · pH | Not applicable. |
| · Viscosity: | |
| · Kinematic viscosity | Not applicable. |
| · dynamic: | Not applicable. |
| · Solubility | |
| · Water: | Fully miscible |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not applicable. |
| · Density and/or relative density | |
| · Density | Not determined |
| · Vapour density | Not applicable. |

· 9.2 Other information

- | | |
|--|------------------------------|
| · Appearance: | |
| · Form: | Fluid |
| · Important information on protection of health and environment, and on safety. | |
| · Self-inflammability: | Product is not selfigniting. |
| · Explosive properties: | Product is not explosive. |
| · Solvent content: | |
| · Organic solvents: | 0.0 % |
| · Change in condition | |
| · Evaporation rate | Not applicable. |

· Information with regard to physical hazard classes

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

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· 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:**

57-50-1 sucrose, pure

Oral	LD50	29,700 mg/kg (rat)
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- **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.

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- **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** Smaller quantities can be disposed with household waste.
- **Uncleaned packagings:**
 - **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.

SECTION 14: Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR/RID, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR/RID, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR/RID, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| <ul style="list-style-type: none"> · Transport/Additional information: | Not dangerous according to the above specifications. |
| <ul style="list-style-type: none"> · 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.

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· 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.

· Department issuing data specification sheet:

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

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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