

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

Printing date 08.10.2023

Version number 1

Revision: 08.10.2023

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

· **1.1 Product identifier**

· **Trade name:** foodproof Salmonella and Cronobacter LyoKits

· **Product variants:**

- KIT230081 / foodproof® Cronobacter Detection LyoKit - LP (Ref. R 602 13-1)
- KIT230082 / foodproof® Cronobacter Detection LyoKit - RP (Ref. R 602 13-2)
- KIT230083 / foodproof® Cronobacter Detection LyoKit - DP (Ref. R 602 13-3)
- KIT230099 / foodproof® Salmonella Detection LyoKit - LP (Ref. R 602 27-1)
- KIT230100 / foodproof® Salmonella Detection LyoKit - LP (Ref. R 602 27-1 L)
- KIT230101 / foodproof® Salmonella Detection LyoKit - RP (Ref. R 602 27-2)
- KIT230102 / foodproof® Salmonella Detection LyoKit - DP (Ref. R 602 27-3)
- KIT230106 / foodproof® Salmonella Enteritidis & Typhimurium Detection LyoKit - LP (Ref. R 602 34-1)
- KIT230107 / foodproof® Salmonella Enteritidis & Typhimurium Detection LyoKit - RP (Ref. R 602 34-2)
- KIT230131 / foodproof® Salmonella plus Cronobacter Detection LyoKit - LP (Ref. R 602 57-1)
- KIT230132 / foodproof® Salmonella plus Cronobacter Detection LyoKit - RP (Ref. R 602 57-2)
- KIT230133 / foodproof® Salmonella plus Cronobacter Detection LyoKit - DP (Ref. R 602 57-3)
- KIT230134 / foodproof® Salmonella Genus plus Enteritidis & Typhimurium Detection LyoKit (Ref. R 602 59-1)
- KIT230135 / foodproof® Salmonella Genus plus Enteritidis & Typhimurium Detection LyoKit (Ref. R 602 59-2)
- KIT230136 / foodproof® Salmonella Genus plus Enteritidis & Typhimurium Detection LyoKit (Ref. R 602 59-3)
- KIT230137 / foodproof® Enterobacteriaceae plus Salmonella Detection LyoKit - LP (Ref. R 602 67-1)
- KIT230138 / foodproof® Enterobacteriaceae plus Salmonella Detection LyoKit - RP (Ref. R 602 67-2)
- KIT230139 / foodproof® Enterobacteriaceae plus Salmonella Detection LyoKit - DP (Ref. R 602 67-3)

· **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

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- **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
  - **Additional information:**  
Please refer to further labelling elements in section 15 of this safety data sheet, if applicable.  
Safety data sheet available on request.
- **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: 50-01-1<br>EINECS: 200-002-3<br>Index number: 607-148-00-0<br>Reg.nr.: 01-2119977063-35-X | guanidinium chloride<br>⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319 | < 2.5% |
|--|---|--------|
- **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**  
Remove contact lenses if possible.  
Keep eye lids open and rinse them with ample amounts of clean running water for at least 15 minutes.  
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.

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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**  
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**  
Avoid contact to eyes, skin and clothes.
- **6.2 Environmental precautions:** 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.  
Keep away from heat and direct sunlight.  
Avoid contact with eyes and skin.
  - **Information about protection against explosions and fires:** No special measures required.
- **Handling**  
Do not eat, drink or smoke while working.  
Wash hands during breaks and at the end of the work.
- **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.

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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**
- **Breathing equipment:** Not required.
- **Hand protection**  
Protective gloves are recommended at frequent and/or long-term skin contact with the product. To avoid skin problems reduce the wearing of gloves to the required minimum.
  - **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 if possibility of liquid splashes exists.
- **Body protection:** Wear suitable protective clothing.

### 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:** Insoluble
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not applicable.
- **Density and/or relative density**
- **Density** Not determined

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· <b>Vapour density</b>	Not applicable.
· <b>9.2 Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Solid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive.
· <b>Solvent content:</b>	
· <b>Organic solvents:</b>	0.0 %
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not applicable.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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.

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>50-01-1 guanidinium chloride</b>		
Oral	LD50	773.6 mg/kg (rat)

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Dermal	LD50	> 2,000 mg/kg (rabbit)
Inhalative	LC50	3.181 mg/l/4h (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.

## SECTION 12: Ecological information

**12.1 Toxicity**

- **Aquatic toxicity:**

**50-01-1 guanidinium chloride**

EC50	1,758 mg/l/48h (fish)
EC50 (static)	11.8 mg/l/72h (Raphidocelis subcapitata)

- **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:**  
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**

Can be burnt with household garbage after consulting with the operator of the waste disposal facility and the pertinent authorities and under adherence to the necessary technical regulations.

- **Uncleaned packagings:**

- **Recommendation:**

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

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### SECTION 14: Transport information

· <b>14.1 UN number or ID number</b> · <b>ADR/RID, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b> · <b>ADR/RID, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b> · <b>ADR/RID, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR/RID, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	Not dangerous according to the above specifications.
· <b>UN "Model Regulation":</b>	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.
  - **REGULATION (EC) No 1907/2006 ANNEX XVII**  
Taking into account the intended use as indicated in Section 1, the relevant entries from Annex XVII are executed.  
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.

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- **National regulations**

- **Water hazard class:**

- **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.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

- **Department issuing data specification sheet:**



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

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2