

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

Printing date 14.11.2023

Version number 3 (replaces version 2)

Revision: 14.11.2023

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

· **1.1 Product identifier**

· **Trade name:** foodproof StarPrep Five Kit

· **Product variants:** KIT230191 / foodproof® StarPrep Five Kit (Ref. S 400 21)

· **Kit Parts:**

Lysis Buffer

Buffer M

Proteinase K / UFI: NH00-60XY-M004-TNVU

· **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**

Laboratory and analytical use / Sample preparation solutions

· **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

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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**



GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

### 2.2 Label elements

#### Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

#### Hazard pictograms



GHS07 GHS08

#### Signal word Danger

#### Hazard-determining components of labelling:

Proteinase K

#### Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

#### Precautionary statements

P261 Avoid breathing dust.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves / eye protection.

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

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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

P312 Call a POISON CENTER/doctor if you feel unwell.

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

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Additional information:

Packaging of whatever capacity that is delivered to the general public shall be fitted with a tactile warning of danger according to EN ISO 11683.

Please refer to further labelling elements in section 15 of this safety data sheet, if applicable.

Contains 2-Chloroacetamide. May produce an allergic reaction.

#### Labelling of packages where the contents do not exceed 125 ml

#### Hazard pictograms



GHS07 GHS08

#### Signal word Danger

#### Hazard-determining components of labelling:

Proteinase K

#### Hazard statements

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

#### Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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- P272 Contaminated work clothing should not be allowed out of the workplace.  
 P280 Wear protective gloves.  
 P284 [In case of inadequate ventilation] wear respiratory protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
 P321 Specific treatment (see on this label).  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.  
 P362+P364 Take off contaminated clothing and wash it before reuse.

### 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:** Kit of reagents for the preparation of DNA for direct use in PCR.

#### Dangerous components:

CAS: 39450-01-6 EINECS: 254-457-8 Index number: 647-014-00-9	Proteinase K ⚠ Resp. Sens. 1, H334; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	50 - 100%
CAS: 79-07-2 EINECS: 201-174-2 Index number: 616-036-00-0 Reg.nr.: 01-2119958971-23-X	2-Chloroacetamide ⚠ Acute Tox. 3, H301; ⚠ Repr. 2, H361f; ⚠ Skin Sens. 1, H317 Specific concentration limit: Skin Sens. 1; H317: C ≥ 0.1 %	< 0.1%

- **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 and call for doctor for safety reasons.  
In case of unconsciousness bring patient into stable side position for transport.
- **After skin contact**  
If skin irritation continues, consult a doctor.  
Instantly wash with water and soap and rinse thoroughly.
- **After eye contact**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.  
Remove contact lenses if possible.
- **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** Use fire fighting measures that suit the environment.

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- **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).  
Ensure adequate ventilation
- **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:**  
Absorb with liquid-binding material (sand, diatomite, universal binders) and disposal in suitable containers.  
Dispose of contaminated material as waste according to section 13.
- **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**  
Put on suitable personal protective equipment.  
Avoid contact with eyes and skin.  
Prevent formation of dust.
- **Information about protection against explosions and fires:** No special measures required.
- **Handling** 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:**  
Keep container tightly closed and store in a dry, cool and well ventilated place.  
Protect from heat and direct sunlight.
    - **Recommended storage temperature:** approx. 15°C to 25°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
  - **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:**  
Approved dust respirators must be used for dusty conditions or if dust levels exceed established standards.

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### · Hand protection



Protective gloves.

Only use chemical-protective gloves with CE-labelling of category III (EN 374).

### · 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

With a lamination strenght of 0,11 mm the permeation time is > 480 min.

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



Tightly sealed safety glasses.

Where dusting potential exist, goggles should be worn.

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

· Physical state	solid / liquid
· Colour:	colourless
· 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
· Auto-ignition temperature:	Product is not selfigniting.
· Decomposition temperature:	Not determined.
· SADT	
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· dynamic:	Not applicable.
· Solubility	
· Water:	Dispersible
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.

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- **Density and/or relative density**
- **Density** Not determined
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Particle characteristics**
- See section 3.

### · 9.2 Other information

- **Appearance:**
- **Form:** solid / liquid
- **Important information on protection of health and environment, and on safety.**
- **Self-inflammability:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive.
- **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
- **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.

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**· LD/LC50 values that are relevant for classification:**
**79-07-2 2-Chloroacetamide**

Oral	LD50	138 mg/kg (rat)
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**· Skin corrosion/irritation**

Causes skin irritation.

**· Serious eye damage/irritation** Causes serious eye irritation.

**· Respiratory or skin sensitisation**

Sensitive persons can possibly have allergic reactions. This is also valid below the fixed levels of exposure.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

**· 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** May cause respiratory irritation.

**· 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:**

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**

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**

16 00 00	WASTES NOT OTHERWISE SPECIFIED IN THE LIST
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16 03 00	off-specification batches and unused products
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16 03 05*	organic wastes containing hazardous substances
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HP4	Irritant - skin irritation and eye damage
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HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP13	Sensitising

· **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.

### SECTION 14: Transport information

· <b>14.1 UN number or ID number</b>	
· <b>ADR/RID, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b>	
· <b>ADR/RID, 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.

· **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.

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- **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:**

- **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**

The phrases specified here are no labelling elements for the product but repeat the properties of the ingredients from section 3.

H301 Toxic if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility.

- **Department issuing data specification sheet:**



This Safety Data Sheet has been drawn up in cooperation with:  
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- **Date of previous version:** 24.04.2019

- **Version number of previous version:** 2

- **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. 3: Acute toxicity – Category 3

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

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

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3