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

Printing date 31.05.2023

Version number 1

Revision: 30.05.2023

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

· 1.1 Product identifier

- · Trade name: foodproof StarPrep Two Kits
 - Product variants: KIT230177 / foodproof® StarPrep Two Kit (Ref. S 400 08.1)
 KIT230186 / foodproof® StarPrep Two 8-Strip Kit (Ref. S 400 17 L)
- **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 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
- · Additional information:
- Contains 2-Chloroacetamide. May produce an allergic reaction.
- Safety data sheet available on request.
- · 2.3 Other hazards
 - · Results of PBT and vPvB assessment
 - **PBT:** Not applicable.
 - *vPvB:* Not applicable.

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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: Aqueous reagent solution for the preparation of DNA for direct use in PCR.

· Dangerous components:

CAS: 79-07-2 EINECS: 201-174-2 Reg.nr.: 01-2119958971-23-X 1, H317

2-Chloroacetamide 🔶 Acute Tox. 3, H301; 🚸 Repr. 2, H361f; 🚸 Skin Sens.

< 0.1%

Specific concentration limit: Skin Sens. 1; H317: $C \ge 0.1 \%$

SECTION 4: First aid measures

- · 4.1 Description of first aid measures General information Remove contaminated clothing immediately. No special measures required.
 - · 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 eve 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.

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 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.
- · 6.3 Methods and material for containment and cleaning up: Send for recovery or disposal in suitable containers. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders). 6.4 Reference to other sections
- See Section 7 for information on safe handling

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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 eves 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:* None.
 - **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:

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
 - The usual precautionary measures should be adhered to general rules for handling chemicals.
- · Breathing equipment: Not required.
- 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 |
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9.1 Information on basic physical and chemical properties
 General Information

· Colour:

Colourless

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| · 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 at 20 °C | ca. 8 | |
| · Solubility | Dianamaikha | |
| · Water: | Dispersible | |
| Density and/or relative density | Not determined | |
| · 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. | |
| Solvent content: | / | |
| · Organic solvents: | 0.0 % | |
| · VOC EU | < 33 % | |
| · Solids content: | < 33 % | |
| 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 | Vaid | |
| flammable gases in contact with water | Void Void | |
| • Oxidising liquids | Void | |
| Oxidising solids Organic peroxides | Void | |
| · Corrosive to metals | Void | |
| Corrosive to metals Desensitised explosives | Void | |
| Descristiscu explusives | volu | |

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.

 \cdot 10.5 Incompatible materials: No further relevant information available.

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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:

79-07-2 2-Chloroacetamide

Oral LD50 138 mg/kg (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
- Sensitive persons can possibly have allergic reactions. This is also valid below the fixed levels of exposure.
- · 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: Generally not hazardous for water.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

• *Recommendation* Smaller quantities can be disposed with household waste.

· European waste catalogue

07 00 00 WASTES FROM ORGANIC CHEMICAL PROCESSES

07 01 00 wastes from the manufacture, formulation, supply and use (MFSU) of basic organic chemicals

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| | wastes not otherwise specified |
| 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 06 | chemicals other than those mentioned in 18 02 05 |

· 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 inform | nation |
|--|--|
| 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 |
| 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 accordin IMO instruments | <i>ng to</i> 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.

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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: Generally not 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 Reglation (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

H301 Toxic if swallowed.

H317 May cause an allergic skin reaction.

H361f Suspected of damaging fertility.

· Department issuing data specification sheet:

DEKRA This Safety Data Sheet has been drawn up in cooperation with: DEKRA Assurance Services GmbH, Hanomagstr. 12, D-30449 Hanover, Germany, phone: (+49) 511 42079 - 0, reach@dekra.com.

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 Abbreviations and acronvms: 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 Sens. 1: Skin sensitisation - Category 1 Repr. 2: Reproductive toxicity - Category 2

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