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

1.1 Product identifier

Trade name: R 602 11-1 foodproof® STEC Screening Lyokit, 5’Nuclease-LP
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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

Test kit

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
BIOTECON Diagnostics GmbH
Hermannswerder Haus 17
14473 Potsdam
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

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

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1.4 Emergency telephone number: Phone: +49 (0) 331-23 00 200

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.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
Description: PCR detection kit of isolated DNA.

Dangerous components: Void
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:** Do not allow to enter drainage system, surface or ground water.
**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.

- **Further information about storage conditions:**
  Store the dark.
  Protect from the effects of light.

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

- **Storage class** 13 (non combustible solids) according TRGS 510

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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

Additional information: The lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures

Wash hands during breaks and at the end of the work.

Breathing equipment: Not required.

Protection of hands:

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.

(Contd. on page 6)
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(Contd. from page 5)

· **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 protection:** Not required.

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

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Solid
    - **Colour:** Different according to colour
    - **Odour:** odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - **Melting point/freezing point:** Not determined
    - **Initial boiling point and boiling range:** Not determined
  - **Flash point:** Not applicable
  - **Inflammability (solid, gaseous)** Not determined.
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### 44.4.6 · Ignition temperature:

**Decomposition temperature:** Not determined.

### 9.2 Other information

**Partition coefficient: n-octanol/water:** Not determined.

**Solvent content:**

- **Organic solvents:** 0.0 %
- **9.2 Other information** No further relevant information available.
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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
  - **Primary irritant effect:**
  - **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.
  - **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
  - **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.
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R 602 23-1 foodproof® Listeria monocytogenes Detection Lyokit, 5’Nuclease-LP  
R 602 23-2 foodproof® Listeria monocytogenes Detection Lyokit, 5’Nuclease-RP  
R 602 27-1 foodproof® Salmonella Detection Lyokit, 5’Nuclease-LP  
R 602 27-2 foodproof® Salmonella Detection Lyokit, 5’Nuclease-RP  
R 602 34-1 foodproof® Salmonella Enteritidis & Typhimurium Lyokit, 5’Nuclease-LP  
R 602 34-2 foodproof® Salmonella Enteritidis & Typhimurium Lyokit, 5’Nuclease-RP  
R 602 40-1 foodproof® Clostridium botulinum Detection Lyokit, 5’Nuclease-LP  
R 602 40-2 foodproof® Clostridium botulinum Detection Lyokit, 5’Nuclease-RP  
R 602 42-1 foodproof® Yeast and Mold Quantification Lyokit, 5’Nuclease-LP  
R 602 42-2 foodproof® Yeast and Mold Quantification Lyokit, 5’Nuclease-RP  
R 602 43-1 foodproof® Porcine Detection Lyokit, 5’Nuclease-LP  
R 602 43-2 foodproof® Porcine Detection Lyokit, 5’Nuclease-RP  
R 602 44-1 foodproof® Vibrio Detection Lyokit, 5’Nuclease-LP  
R 602 44-2 foodproof® Vibrio Detection Lyokit, 5’Nuclease-RP

- **Aspiration hazard** Based on available data, the classification criteria are not met.

**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.

- **Additional ecological information:**

  - **General notes:**
    Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.  
    Do not allow product to reach ground water, water bodies or sewage system.  
    Danger to drinking water if even small quantities leak into soil.

  - **12.5 Results of PBT and vPvB assessment**

    - **PBT:** Not applicable.
    - **vPvB:** Not applicable.

- **12.6 Other adverse effects**  
  No further relevant information available.

**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.
**SECTION 14: Transport information**

- **14.1 UN-Number**
  - ADR, ADN, IMDG, IATA: Void

- **14.2 UN proper shipping name**
  - ADR, ADN, IMDG, IATA: Void

- **14.3 Transport hazard class(es)**
  - ADR, ADN, IMDG, IATA: Void
  - Class: Void

- **14.4 Packing group**
  - ADR, IMDG, IATA: Void

- **14.5 Environmental hazards:**
  - Marine pollutant: No

- **14.6 Special precautions for user**
  - Not applicable.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**
  - Not applicable.

- **Transport/Additional information:**
  - Not dangerous according to the above specifications.

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- R 602 12-2 foodproof® STEC Identification LyoKit– 5’Nuclease –RP
- R 602 13-1 foodproof® Cronobacter Detection LyoKit -5’Nuclease-LP
- R 602 13-2 foodproof® Cronobacter Detection LyoKit -5’Nuclease-RP
- R 602 17-1 foodproof® GMO Screening 1 LyoKit -5’Nuclease-LP
- R 602 17-2 foodproof® GMO Screening 1 LyoKit -5’Nuclease-RP
- R 602 18-1 foodproof® GMO Screening 2 LyoKit -5’Nuclease-LP
- R 602 18-2 foodproof® GMO Screening 2 LyoKit -5’Nuclease-RP
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- R 602 20-2 foodproof® Listeria Genus Detection LyoKit, 5’Nuclease-RP
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**SECTION 15: Regulatory information**

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Labelling according to Regulation (EC) No 1272/2008 Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 65
- National regulations
- Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water.

**Substances of very high concern (SVHC) according to REACH, Article 57**
None of the ingredients is contained.

**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.

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Department issuing data specification sheet:
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Abbreviations and acronyms:
ADR: Accord européen sur le transport 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)
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.