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

- 1.1 Product identifier
  - Trade name: R 602 45-1 foodproof® Legionella Quantification LyoKit, 5'Nuclease-LP
  - R 602 45-2 foodproof® Legionella Quantification LyoKit, 5'Nuclease-RP

- 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

- 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

  GHS05 corrosion

  Eye Dam. 1  H318  Causes serious eye damage.

- 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

  GHS05

  - Signal word Danger

  - Hazard-determining components of labelling:
    Triton X-100
  - Hazard statements
    H318 Causes serious eye damage.
  - Precautionary statements
    P280  Wear eye protection / face protection.
Trade name: R 602 45-1 foodproof® Legionella Quantification LyoKit, 5’Nuclease-LP
R 602 45-2 foodproof® Legionella Quantification LyoKit, 5’Nuclease-RP

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

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 kit for the detection of specific organisms.
    Target organisms as specified on separate enclosure.
  - Dangerous components:
    - CAS: 57-50-1 sucrose, pure
      - substance with a Community workplace exposure limit 10 - 25%
    - CAS: 9002-93-1 Triton X-100
      - Eye Dam. 1, H318; Acute Tox. 4, H302
      - ≥ 3 - < 10%
    - SVHC
      - 9002-93-1 Triton X-100
    - 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.
### 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.
    
    - **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
    
    | Component          | Short-term value | Long-term value |
    |--------------------|------------------|-----------------|
    | 57-50-1 sucrose, pure | 20 mg/m³         | 10 mg/m³        |
    
  - **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.

Penetration time of glove material
The exact breakthrough 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.

- Decomposition temperature: Not determined.

- Self-inflammability: Product is not selfigniting.

- Explosive properties: Product is not explosive.

- Critical values for explosion:
  - Lower: Not determined.
  - Upper: Not determined.

- Vapour pressure: Not applicable.

- Density
  - Vapour density Not determined
  - Evaporation rate Not applicable.

- Solubility in / Miscibility with
  - Water: Insoluble

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

- Viscosity:
  - dynamic: Not applicable.
  - kinematic: Not applicable.
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**: Causes serious eye damage.
  - **Respiratory or skin sensitisation**: Based on available data, the classification criteria are not met.
  - **CMR effects (carcinogenicity, 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.
  - **Aspiration hazard**: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 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.
### 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.

### 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

- **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.

- **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.
  - 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**

  - 9002-93-1 Triton X-100

(Contd. on page 7)
Trade name: R 602 45-1 foodproof® Legionella Quantification LyoKit, 5'Nuclease-LP
R 602 45-2 foodproof® Legionella Quantification LyoKit, 5'Nuclease-RP

(Contd. from page 6)

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.

- Relevant phrases
  H302 Harmful if swallowed.
  H318 Causes serious eye damage.

- Department issuing data specification sheet:
  This Material 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 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
  Acute Tox. 4: Acute toxicity – Category 4
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1