

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

Printing date 15.03.2017

Version number 1

Revision: 15.03.2017

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

- **1.1 Product identifier**
- **Trade name:** foodproof® Hepatitis A Virus Detection Kit, 5'Nuclease
- **Article number:** R 302 37
- **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** Detection System Solutions
- **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**
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:** Qualitative detection of hepatitis A virus RNA.

- **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	50 - 100%
CAS: 57-50-1 EINECS: 200-334-9	sucrose, pure substance with a Community workplace exposure limit	2.5-<10%
CAS: 9002-93-1	Triton X-100 ☠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302	≤ 0.25%

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· **SVHC**

9002-93-1 Triton X-100

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 eye 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:**
Do not allow to enter drainage system, surface or ground water.
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
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.

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- **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.
- **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:**

56-81-5 glycerol

WEL (Great Britain)	Long-term value: 10 mg/m ³
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57-50-1 sucrose, pure

WEL (Great Britain)	Short-term value: 20 mg/m ³ Long-term value: 10 mg/m ³
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· DNELs

56-81-5 glycerol

Oral	DNEL (consumer, long-term, systemic)	229 mg/kg bw/day (human)
Inhalative	DNEL (worker, long-term, local)	56 mg/m ³ (human)
	DNEL (consumer, short-term, local)	33 mg/m ³ (human)

- **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

The usual precautionary measures should be adhered to general rules for handling chemicals.

- **Breathing equipment:** Not necessary if room is well-ventilated.

- **Protection of hands:** 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 protection:** Safety glasses recommended during refilling.

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

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Liquid
Colour:	Different according to colour
Odour:	odourless

· **pH-value:** Not determined.

· **Change in condition**

Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	> 100 °C

· **Flash point:** Not applicable

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive.

· **Density** Not determined

· **Solubility in / Miscibility with Water:**

Fully miscible

· **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.

· **LD/LC50 values that are relevant for classification:**

56-81-5 glycerol

Oral	LD50	27200 mg/kg (rat)
Dermal	LD50	56750 mg/kg (guinea pig)
Inhalative	LC50	> 11 mg/l/1h (rat)

· **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 (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.

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- **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

· Aquatic toxicity:

56-81-5 glycerol

EC50 (static)	1955 mg/l/48h (Daphnia magna)
IC5	> 10000 mg/l/7d (Scenedesmus quadricauda)
EC5	> 10000 mg/l/16h (Pseudomonas putida)
EC5	3200 mg/l/72h (Entosiphon sulcatum)
LC50 (static)	54000 mg/l/96h (Oncorhynchus mykiss)

- **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 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **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** Proceed according to local, official regulations.
- **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 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 | |
| · Class | Void |

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· 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**
- **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: 46b
- **National regulations**
- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly 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.

- **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:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
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

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ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
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
Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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