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

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

· **1.1 Product identifier**

· **Trade name:** **food**proof/**vet**proof **Virus Detection Kits**

· **Product variants:**
KIT230054 - foodproof® Hepatitis A Virus Detection Kit (Ref. R 302 37)
KIT230055 - foodproof® Norovirus Detection Kit (GI, GII) (Ref. R 302 38.1)
KIT230056 - foodproof® Norovirus (GI, GII) plus Hepatitis A Virus Detection Kit (Ref. R 302 50)
KIT230156 - vetproof® PRRSV Detection Kit (Ref. RDK 100 72.2)

· **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**
PCR kit for the qualitative detection of certain viruses using real-time PCR.

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
Hygiena Diagnostics GmbH
Hermannswerder Haus 17
14473 Potsdam
GERMANY
Phone: +49 (0) 331-23 00 200
www.hygiena.com

BIOTECON Diagnostics GmbH
Hermannswerder Haus 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

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

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· ***vPvB:*** Not applicable.

SECTION 3: Composition/information on ingredients

· ***3.2 Mixtures***
· ***Description:***
PCR-kit for the qualitative detection of RNA from certain viruses using real-time PCR
Target organisms as specified on separate enclosure.

· ***Dangerous components:***		
CAS: 56-81-5 EINECS: 200-289-5 Reg.nr.: 01-2119471987-18-X	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%

· ***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.
No special measures required.
· ***After inhalation*** Supply fresh air; consult doctor in case of symptoms.
· ***After skin contact***
Wash with water and soap.
If skin irritation continues, consult a doctor.
· ***After eye contact***
Rinse opened eye for several minutes under running water.
In case of permanent aches and pains please go and see the doctor.
· ***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.
· ***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.
· ***6.3 Methods and material for containment and cleaning up:***
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
Send for recovery or disposal in suitable containers.
Dispose of contaminated material as waste according to section 13.

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· ***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.
· ***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.
· ***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:***
WEL: workplace exposure limit
OEL: Occupational Exposure Limit

56-81-5 glycerol	
WEL (Great Britain)	Long-term value: 10 mg/m³
57-50-1 sucrose, pure	
WEL (Great Britain)	Short-term value: 20 mg/m³ Long-term value: 10 mg/m³

· ***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/m³ (human)
	DNEL (consumer, short-term, local)	33 mg/m³ (human)

· ***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***
Wash hands during breaks and at the end of the work.
· ***Breathing equipment:*** Not necessary if room is well-ventilated.
· ***Hand protection***
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

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· ***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

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Physical state***	Fluid
· ***Colour:***	Colourless
· ***Odour:***	odourless
· ***Odour threshold:***	Not determined.
· ***Melting point/freezing point:***	0 °C
· ***Boiling point or initial boiling point and boiling range***	100 °C (7732-18-5 water, distilled, conductivity or of similar purity)
· ***Flammability***	Not applicable.
· ***Lower and upper explosion limit***	
· ***Lower:***	Not determined.
· ***Upper:***	Not determined.
· ***Flash point:***	Not applicable
· ***Decomposition temperature:***	Not determined.
· ***SADT***	
· ***pH***	Not determined.
· ***Viscosity:***	
· ***Kinematic viscosity***	Not determined.
· ***dynamic at 20 °C:***	0.952 mPas
· ***Solubility***	
· ***Water:***	Fully miscible
· ***Partition coefficient n-octanol/water (log value)***	Not determined.
· ***Vapour pressure at 20 °C:***	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
· ***Density and/or relative density***	
· ***Density at 20 °C***	1 g/cm³
· ***Relative density***	Not determined.
· ***Vapour 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.

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· ***Solvent content:***	
· ***Organic solvents:***	1.5 %
· ***Change in condition***	
· ***Evaporation rate***	Not determined.
· ***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.

· ***LD/LC50 values that are relevant for classification:***		
56-81-5 glycerol		
Oral	LD50	27,200 mg/kg (rat)
Dermal	LD50	56,750 mg/kg (guinea pig)
Inhalative	LC50	> 11 mg/l/1h (rat)
57-50-1 sucrose, pure		
Oral	LD50	29,700 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*** Based on available data, the classification criteria are not met.
· ***Germ cell mutagenicity*** Based on available data, the classification criteria are not met.

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· ***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:***	
56-81-5 glycerol	
EC50 (static)	1,955 mg/l/48h (Daphnia magna)
IC5	> 10,000 mg/l/7d (Scenedesmus quadricauda)
EC5	> 10,000 mg/l/16h (Pseudomonas putida)
EC5	3,200 mg/l/72h (Entosiphon sulcatum)
LC50 (static)	54,000 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.
· ***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:***
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.

SECTION 13: Disposal considerations

· ***13.1 Waste treatment methods***
· ***Recommendation***
Proceed according to local, official regulations.
Smaller quantities can be disposed with household waste.
The waste code numbers mentioned are recommendations based on the probable use of the product.

· ***European waste catalogue***	
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 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 07	chemicals other than those mentioned in 18 01 06
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)

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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:***
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.
· ***Recommended cleaning agent:*** Water, if necessary with cleaning agent.

SECTION 14: Transport information

· ***14.1 UN number or ID number***	
· ***ADR/RID, IMDG, IATA***	Void
· ***14.2 UN proper shipping name***	
· ***ADR/RID, 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 according to IMO instruments***	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.

· ***Annex II - REPORTABLE EXPLOSIVES PRECURSORS***

None of the ingredients is listed.

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

· ***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.

· ***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 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)
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