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

Printing date 12.11.2020

Version number 1

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

· 1.1 Product identifier

· Trade name: foodproof Magnetic Preparation Kit III

· Article number: S 400 13.2, S 400 13.2 L

• UFI: Binding Buffer: 6800-P0VS-P00N-TN4N Wash Buffer I: TF00-Q08K-900N-4A9S Wash Buffer II: AC00-60K6-0004-GYQQ Proteinase K: NH00-60XY-M004-TNVU Elution Buffer: WM00-Q0NC-W00N-F0FW

• 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 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

GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS07			
Acute Tox. 4	H302	Harmful if swallowed.	
Acute Tox. 4	H332	Harmful if inhaled.	
Skin Irrit. 2	H315	Causes skin irritation.	
Eye Irrit. 2	H319	Causes serious eye irritation.	
Skin Sens. 1	H317	May cause an allergic skin reaction.	
STOT SE 3	H335	May cause respiratory irritation.	
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.	
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Trade name: Toodproof Magnetic Preparation Kit III	
	(Control from mono 1)
· Additional information:	(Contd. from page 1)
Set composed of separate, different vials.	
Binding Buffer:	
Achtung/Warning	
Skin Sens. 1: H317	
Wash Buffer I:	
Achtung/Warning	
Acute Tox. 4: H302+H332	
Skin Irrt. 2: H315	
Eye Irrit. 2: H319	
Skin Sens. 1: H317	
Wash Buffer II:	
Achtung/Warning Skin Sens. 1: H317	
Skin Sens. 1: H317	
Proteinase K:	
Gefahr/Danger	
Resp. Sens. 1: H334	
Skin Irrt. 2: H315	
Eye Irrit. 2: H319	
Skin Sens. 1: H317	
STOT SE 3: H335	
Elution Buffer:	
Achtung/Warning	
Skin Sens. 1: H317	
· 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	
GHS07 GHS08	
· Signal word Danger	
C C	
Hazard-determining components of labelling:	
guanidinium chloride	
Proteinase, Tritirachium album serine	
ammonium chloride	
2-methyl-2H-isothiazol-3-one	
· Hazard statements	
H302+H332 Harmful if swallowed or if inhaled.	
H315 Causes skin irritation.	
H319 Causes serious eye irritation.	te la alla al
H334 May cause allergy or asthma symptoms or breathing difficulties if	innaleo.
H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.	
H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects.	
· Precautionary statements	
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.	
P264 Wash thoroughly after handling.	
P280 Wear protective gloves / eye protection / face protection.	
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you fe	el unwell.
P302+P352 IF ON SKIN: Wash with plenty of water.	
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P304+P340 P305+P351+	(Contd. from page 2) IF INHALED: Remove person to fresh air and keep comfortable for breathing. P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact-
	lenses, if present and easy to do. Continue rinsing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/ international regulations.
 Additional in 	formation:
	whatever capacity that is delivered to the general public shall be fitted with a tactile nger according to EN ISO 11683.
	packages where the contents do not exceed 125 ml
· Hazard pict	
nazaru pici	Ugranis
\wedge	
GHS07 GI	HS08
· Signal word	Dangor
-	-
· Hazard-dete	ermining components of labelling:
guanidinium	chloride
Proteinase,	Tritirachium album serine
ammonium o	
2-methvl-2H	-isothiazol-3-one
· Hazard state	
	ause allergy or asthma symptoms or breathing difficulties if inhaled.
	ause an allergic skin reaction.
	ul to aquatic life with long lasting effects.
	ary statements
	Avoid breathing dust/fume/gas/mist/vapours/spray.
	Wear protective gloves / eye protection / face protection.
	IF ON SKIN: Wash with plenty of water.
	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	Dispose of contents/container in accordance with local/regional/national/international
	regulations.
 2.3 Other haza 	
 Results of PL 	BT and vPvB assessment
 • PBT: Not ap 	plicable.
• <i>vPvB:</i> Not a	
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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: 39450-01-6 EINECS: 254-457-8	Proteinase, Tritirachium album serine Resp. Sens. 1, H334; () Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	50 - 100%
CAS: 50-01-1 EINECS: 200-002-3 Reg.nr.: 01-2119977063-35-X	guanidinium chloride Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319	50 - 100%
CAS: 12125-02-9 EINECS: 235-186-4 Reg.nr.: 01-2119489385-24-X	ammonium chloride Acute Tox. 4, H302; Eye Irrit. 2, H319	10 - 25%
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CAS: 2682-20-4	2-methyl-2H-isothiazol-3-one	≥ 0.25 - < 1%
EINECS: 220-239-6 Reg.nr.: 01-2120764690-50-X	 Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; Skin Corr. 1B, H314; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); Skin Sens. 1A, H317; STOT SE 3, H335 Specific concentration limit: Skin Sens. 1A; H317: C ≥ 0.0015 % 	
	cetrimonium, salts ♦ Eye Dam. 1, H318; ♦ Aquatic Acute 1, H400 (M=100); ↑ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	≥ 0.025 - < 0.25%

· 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
- Wash with water and soap.

If skin irritation continues, consult a doctor.

· After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

- After swallowing
- Rinse out mouth and then drink plenty of water. 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

The product itself does not burn.

- Use fire fighting measures that suit the environment.
- For safety reasons unsuitable extinguishing agents None known.
- · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire. Inhalation of combustion gases may cause serious health hazards.

- · 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained breathing apparatus.
- · Additional information

Collect contaminated fire fighting water separately. It must not enter drains. Provide sufficient fire fighting water retention.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. Avoid contact with the product.

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- (Contd. from page 4) · 6.2 Environmental precautions: Do not allow product to reach sewage system or water bodies. · 6.3 Methods and material for containment and cleaning up:
- Absorb liquid components with liquid-binding material. Send for recovery or disposal in suitable containers.
- 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. Prevent formation of dust.

· 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.

Recommended storage temperature: < 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:

12125-02-9 ammonium chloride

WEL (Great Britain) Short-term value: 20 mg/m³

- Long-term value: 10 mg/m³ OEL (Ireland)
 - Short-term value: 20 mg/m³
 - Long-term value: 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 when used as intended.

Use a breathing protection if high concentrations are present.

- Short term filter device:
- Filter P2.
- · Protection of hands:

Use gloves of stable material (i.e. nitril rubber).

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Protective gloves.

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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

In case of a layer thickness of 0.11 mm the penetration time is longer than 480 minutes.

• 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:*



Tightly sealed safety glasses.

· Body protection: Wear suitable protective clothing.

SECTION 9: Physical and chemical properties		
9.1 Information on basic physical a · General Information	nd chemical properties	
· Appearance:		
· Form:	Fluid	
· Colour:	Colourless	
· Odour:	Light	
· Odour threshold:	Not determined.	
· pH-value:	Not determined.	
 Change in condition Melting point/freezing point: Initial boiling point and boiling ratio 	Not determined ange: 100 °C	
· 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.	

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· Vapour pressure at 20 °C:	23 hPa	
· Density	Not determined	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
· Water:	Soluble	
· Partition coefficient: n-octanol/	water: Not determined.	
· Viscosity:		
· dynamic:	Not applicable.	
· kinematic:	Not applicable.	
 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

Harmful if swallowed or if inhaled.

· LD/LC50 values that are relevant for classification:

50-01-1 guanidinium chloride

- Oral LD50 773.6 mg/kg (rat)
- Dermal LD50 > 2,000 mg/kg (rabbit)
- Inhalative LC50 3.181 mg/l/4h (rat)

Primary irritant effect:

- Skin corrosion/irritation
- Causes skin irritation.
- · Serious eye damage/irritation
- Causes serious eye irritation.
- Respiratory or skin sensitisation

Sensitizing effect is possible by skin contact and/or inhalation by prolonged exposure. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

- · 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
- May cause respiratory irritation.
- STOT-repeated exposure Based on available data, the classification criteria are not met.

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

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

50-01-1 guanidinium chloride

EC50 1,758 mg/l/48h (Leuciscus idus)

EC50 (static) 11.8 mg/l/72h (Pseudokirchneriella subcapitata)

• 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 danger class 3 (German Regulation) (Self-assessment): extremely hazardous for water. Do not allow product to reach ground water, water bodies or sewage system, even in small guantities.

Danger to drinking water if even extremely 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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

The waste code numbers mentioned are recommendations based on the probable use of the product.

· Europea	· 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		
07 01 99	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 05*	chemicals consisting of or containing hazardous substances		
HP4	Irritant - skin irritation and eye damage		
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity		
HP6	Acute Toxicity		
HP13	Sensitising		
HP14	Ecotoxic		

· Uncleaned packagings:

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings. Non contaminated packagings can be used for recycling.

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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 · ADR/ADN, IMDG, IATA	Void	
 14.2 UN proper shipping name ADR/ADN, IMDG, IATA 	Void	
 14.3 Transport hazard class(es) 		
· ADR/ADN, ADN, IMDG · Class	Void	
· IATA · Class	Void Not Restricted.	
· 14.4 Packing group · ADR/ADN, 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
- 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.

· National regulations

· Water hazard class: Water danger class 3 (Self-assessment): extremely 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.

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(Contd. from page 9) · Relevant phrases H301 Toxic if swallowed. H302 Harmful if swallowed. H311 Toxic in contact with skin. H314 Causes severe skin burns and eve damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H319 Causes serious eye irritation. H330 Fatal if inhaled. H332 Harmful if inhaled. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. · Department issuing data specification sheet: DEKRA 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. © DEKRA Assurance Services GmbH. Changing this documents is subject to explicit acceptance by DEKRA Assurance Services GmbH. 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) 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 - oral - Category 3 Acute Tox. 4: Acute toxicity - oral - Category 4 Acute Tox. 2: Acute toxicity - inhalation - Category 2 Skin Corr. 1B: Skin corrosion/irritation - Category 1B Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 Resp. Sens. 1: Respiratory sensitisation - Category 1 Skin Sens. 1: Skin sensitisation - Category 1 Skin Sens. 1A: Skin sensitisation - Category 1A STOT SE 3: Specific target organ toxicity (single exposure) - Category 3 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3