MATERIAL SAFETY DATA SHEET

according to 1907/2006 EC, Article 31

MegaELISA® CRYPTO

DIAGNOSTIK MEGACOR
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1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name **MegaELISA® CRYPTO**
Art. No. 870096EG1

1.2 Relevant identified uses of the substance or mixture and uses advised against

- Enzyme immunoassay for the qualitative detection of *Cryptosporidium parvum* in feces of pocket pets, pets and farm animals.
- *In vitro* diagnosticum.
- Identified use (PROC15): Use as laboratory reagent.
- Only for commercial users.

1.3 Details of the supplier of the safety data sheet

MEGACOR Diagnostik GmbH
Lochauer Str. 2
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Tel.: +43 5573 85400
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E-Mail: info@megacor.at

1.4 Emergency telephone number

Tel.: +43 5573 85400 only available during normal business hours (Mon – Fri, 8 am – 4:30 pm)

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Wash buffer 10×
Classification according to Regulation (EC) No 1272/2008
GHS08 Health hazard
STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.
Information concerning particular hazards for human and environment
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
Classification system
The classification is according to the latest edition of the EU lists, and extended by company and literature data.

2.2 Label elements

Wash buffer 10×
Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.
Hazard pictograms


GHS08

Signal wording
Warning
Hazard-determining components of labelling
Thimerosal
Hazard statements
H373 May cause damage to organs through prolonged or repeated exposure
Precautionary statements
P260 Do not breathe dust/fume/gas/mist/vapours/spray.

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P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

3 COMPOSITION/INFORMATION OF INGREDIENTS

3.1 Substances

The product contains mixtures.

3.2 Mixtures

Wash buffer 10×
Mixture, consisting of following components:

REACH registration number	EINECS	CAS no.	Name	Percent	Symbol	H sentences
not available	200-210-4	54-64-8	Thimerosal	≤ 0.1 %	 Danger!	H300, H310, H330, H373, H410

Conjugate 1
Mixture, consisting of following components:

REACH registration number	EINECS	CAS no.	Name	Percent	Symbol	H sentences
not available	214-478-5	1132-61-2	4-morpholinpropane-sulfonic acid (MOPS)	1–2.5 %	 Attention!	H315, H319, H335

Stop solution
Mixture of substances with non-hazardous additions.

REACH registration number	EINECS	CAS no.	Name	Percent	Symbol	H sentences
01-2119458838-20-XXXX	231-639-5	7664-93-9	Sulfuric acid 95–97 %	2.5–5 %	 Danger!	H290, H314

For the wording of the listed hazard phrases, refer to section 16.

4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water and rinse thoroughly. Consult a physician.

In case of eye contact
Rinse opened eye thoroughly with plenty of water for at least 15 minutes and consult a physician.

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If swallowed
Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

Wash buffer 10×
No further relevant information available.

Stop solution
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents
- Wash buffer 10×: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

- Wash buffer 10×: During heating or in case of fire, poisonous gases are produced.

5.3 Advice for firefighters

Protective equipment: Mouth respiratory protective device.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Do not inhale vapors/mist/gas. Mount respiratory protective device. Ensure adequate ventilation.

6.2 Environmental precautions

Dilute with plenty of water. Do not allow to enter sewers, 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, sawdust). Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.

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 disposal information.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.
Information about fire and explosion protection: Keep respiratory protective device available.
No smoking, eating, drinking or chewing gum chewing. No storage of food or drink in the laboratories. Wash hands after work. Take off the work clothes before entering break rooms. Keep away from sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: No special requirements.
Information about storage in one common storages facility: Storage at 2–8 °C is recommended.
Further information about storage conditions: None.

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7.3 Specific end user(s)

Application only according to the instructions for use.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

EINECS	Name	Component	WEL
7664-93-9	Sulfuric acid	Stop solution	Long-term value: 0.05 mg/m³ (mist, defined as thoracic fraction)

Additional information
The lists valid during the making were used as basis.

8.2 Exposure controls

The usual precautionary measures should be adhered to when handling chemicals.
Pregnant women should avoid inhalation and skin contact.

Personal protective equipment

- General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Store protective clothing separately.
- Respiratory protection: Not required.


Protection of hands: Protective gloves

- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. 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 exakt break-through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- For the permanant contact gloves made of the following materials are suitable: Nitrile rubber, NBR
- Recommended thickness of the material: ≥ 0.11 mm
- Value for the permeation: Level ≤ 480
- As protection from splashes gloves made of the following materials are suitable: Nitrile rubber, NBR
- Recommended thickness of the material: ≥ 0.11 mm
- Value for the permeation: Level ≤ 480


Eye protection: Tightly sealed goggles

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Component	Appearance form	Colour	Odour, odour threshold	pH value	Melting point
Sample dilution buffer	fluid	blue	characteristic, not determined	not determined	undetermined
Wash buffer 10×	fluid	colourless	characteristic, not determined	not determined	undetermined
Positive Control	fluid	colourless	characteristic, not determined	not determined	0°C
Negative Control	fluid	blue	characteristic, not determined	not determined	undetermined
Conjugate 1	fluid	blue	characteristic, not determined	not determined	0°C
Conjugate 2	fluid	orange	characteristic, not determined	not determined	0°C
Substrate	fluid	colourless	characteristic, not determined	not determined	0°C
Stop solution	fluid	colourless	characteristic, not determined	not determined	0°C

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Component	Boiling point	Flash point	Flammability	Ignition temperature	Self-Igniting
Sample dilution buffer	100 °C	not applicable	not applicable	not determined	not self-igniting
Wash buffer 10×	100 °C	not applicable	not applicable	not determined	not self-igniting
Positive Control	100 °C	not applicable	not applicable	not determined	not self-igniting
Negative Control	100 °C	not applicable	not applicable	not determined	not self-igniting
Conjugate 1	undetermined	111 °C	not applicable	not determined	not self-igniting
Conjugate 2	100 °C	not applicable	not applicable	not determined	not self-igniting
Substrate	> 100 °C	not applicable	not applicable	not determined	not self-igniting
Stop solution	100 °C	not applicable	not applicable	not determined	not self-igniting

Component	Danger of explosion	Vapour pressure (20 °C)	Relative density (20 °C)	Solubility in / miscibility with water
Sample dilution buffer	none	23 hPa	not determined	not miscible / difficult to mix
Wash buffer 10×	none	23 hPa	not determined	fully miscible
Positive Control	none	23 hPa	not determined	fully miscible
Negative Control	none	23 hPa	not determined	fully miscible
Conjugate 1	none	23 hPa	not determined	fully miscible
Conjugate 2	none	23 hPa	not determined	not miscible / difficult to mix
Substrate	none	23 hPa	0.99972 g/cm³	fully miscible
Stop solution	none	23 hPa	1.042 g/cm³	fully miscible

Component	Viscosity	Solvent content	Solid content
Sample dilution buffer	not determined	organic solvents 0 % / water 86.5 %	3.5 %
Wash buffer 10×	not determined	organic solvents 0 % / water 90.4 %	9.6 %
Positive Control	not determined	organic solvents 0 % / water 100 %	none
Negative Control	not determined	organic solvents 0 % / water 86.5 %	3.5 %
Conjugate 1	not determined	organic solvents 0 % / water 97.5 %	99.6 %
Conjugate 2	not determined	organic solvents 0 % / water 100 %	none
Substrate	not determined	organic solvents 0 % / water 99.9 %	0.1 %
Stop solution	not determined	organic solvents 0 % / water 95.1%	none

9.2 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

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.

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10.6 Hazardous decomposition products

No dangerous decomposition products known.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Component	LD/LC values relevant for classification	value	species
Thimerosal	LD_{50} (oral)	75 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.

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
May cause damage to organs through prolonged or repeated exposure.

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

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

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): slighly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

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12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation
Autoclaving is recommended.
Disposal must be made according to official regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging
Disposal must be made according to official regulations.

Recommended cleansing agents
Water, if necessary together with cleansing agents.

14 TRANSPORT INFORMATION

14.1 UN number

ADR/RID: -- ADN/IMDG: -- IATA: --

14.2 UN proper shipping name

ADR/RID: No dangerous goods. ADN/IMDG: No dangerous goods. IATA: No dangerous goods.

14.3 Transport hazard class(es)

ADR/RID: -- ADN/IMDG: -- IATA: --

14.4 Packing group

ADR/RID: -- ADN/IMDG: -- IATA: --

14.5 Environmental hazards

ADR/RID: no ADN/IMDG: Marine pollutant no. IATA: no

14.6 Special precautions for users

Not applicable

14.7 Transport in bulk according to Annex II of Marpol 73/78 and the IBC Code

The product is only delivered and transported in traffic-approved packaging.

Transport/additional information
Not dangerous according to the above specifications.

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: 3, 18

National regulations
Water hazard class: Water hazard class I (Self-assessment): slightly hazardous for water.

15.2 Chemical safety assessment:

A chemical Safety Assessment has not been carried out.

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16 OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee of any specific product features and shall not establish a legally valid contractual relationship.

Handle used device with care and consider potential capability of transmitting infectious diseases.

Relevant phrases

H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (division of the American Chemical Society)
EINECS	European Inventory of Existing Commercial Chemical Substances
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
IATA	Intarnational Air Transport Association
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG	International Maritime Code for Dangerous Goods
LC_{50}	Lethal concentration, 50 percent
LD_{50}	Lethal dose, 50 percent
PBT	Persistent, Bioaccumulative and Toxic
PROC15	Descriptor List for Process Categories
RID	Règlement concernant le transport international ferroviaire de marchandises dangereuses (Regulations concerning the International Carriage of Dangerous Goods by Rail)
STOT RE 2	Specific target organ toxicity (repeated exposure) – Category 2
STOT	Specific target organ toxicity
vPvB	very Persistent and very Bioaccumulative
WEL	Workplace Exposure Limits