

MATERIAL SAFETY DATA SHEET

according to 1907/2006 EC, Article 31

MegaELISA® ANAPLASMA phagocytophilum



Lochauer Str. 2
A-6912 Hörbranz
AUSTRIA

Fon: (+43) 5573 85400
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Version 06/2024

Valid from 05/2024

Revision 03.06.2024

Previous version 05/2024

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

1.1 Product identifier

Product name MegaELISA® ANAPLASMA phagocytophilum

Art. No. 600096EK1 (96's) / 600048EK1 (48's)

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

- Enzyme immunoassay for the qualitative detection of IgG antibodies against *Anaplasma phagocytophilum* in plasma or serum of the dog.
- *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 1 406 43 43

Vergiftungszentrale (VIZ) Gesundheit Österreich GmbH (GÖG), Stubenring 6, 1010 Wien, Austria

www.goeg.at/Vergiftungsinformation

2 HAZARDS IDENTIFICATION

	Components	96's kit	48's kit	Hazardous ingredient	Possible hazards
1.	1 ELISA plate, coated with recombinant <i>Anaplasma phagocytophilum</i> antigens	12 strips with 8 wells	6 strips with 8 wells	–	Although it is not classified as hazardous according to the European Regulation (EC) 1272/2008, the product should be handled with the usual care for all chemicals, in order to avoid synergistic effects. Because of the preservative it may be dangerous for water organisms.
2.	Sample dilution buffer	50 ml	25 ml	Proclin™ 300 (CAS 55965-84-9) at a concentration below the concentration limit shown on the CLP.	
3.	Wash buffer	50 ml	25 ml		
4.	Positive Control	1 ml	0.5 ml		
5.	Negative Control	1 ml	0.5 ml		
6.	Conjugate	12 ml	6 ml	H ₂ O ₂ (CAS 7722-84-1), TMB (CAS 54827-17-7, Acute toxicity type 4) at a concentration below the concentration limit shown on the CLP.	
7.	Substrate	12 ml	6 ml		
8.	Stop solution	15 ml	8 ml	0.2 M Sulfuric acid	According to EC regulation 1272/2008 (CLP), this mixture is classified as not hazardous. A corrosive effect cannot be ruled out because of the pH value.

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DIAGNOSTIK
MEGACOR

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	Components	96's kit	48's kit	Hazardous ingredient	Possible hazards
9.	Cover foil	1	1	–	–
10.	Evaluation sheet	1	1	–	–
11.	Instructions for use	1	1	–	–

3 COMPOSITION / INFORMATION OF INGREDIENTS

3.1 Substances

Not relevant (mixture).

3.2 Mixtures

Mixture of substances with non-hazardous additions.

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

Take off contaminated clothing.

If inhaled

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

Rinse skin with water/shower. In case of skin irritation, consult a physician.

Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eye lids apart. In case of eye irritation consult an ophthalmologist.

Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Irritation, Irritant effects

4.3 Indication of any immediate medical attention and special treatment needed

none

5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents



Co-ordinate firefighting measures to the fire surroundings!

Water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with skin, eyes and clothes. Do not breathe vapour / spray.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. The product is an acid. Before discharge into sewage plants the product normally needs to be neutralised.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill – Covering of drains

Advice on how to clean up a spill – Absorb with liquid-binding material (sand, diatomaceous earth, acid or universal binding agents).

Other information relating to spills and releases

– Place in appropriate containers for disposal.

6.4 Reference to other sections

See Section 5 for information on hazardous combustion products.

See Section 8 for information on personal protection equipment.

See Section 10 for information on incompatible materials.

See Section 13 for disposal information.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

No special measures are necessary.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Specific designs for storage rooms or vessels

Recommended storage temperature: 2–8°C

7.3 Specific end use(s)

No information available.

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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/m ³ (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.

Individual protection measures (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.



Skin protection: Wear 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 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 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 minutes (permeation level 6)
- As protection from splashes gloves made of the following materials are suitable: Nitrile rubber, NBR
- Recommended thickness of the material: ≥ 0.11 mm



Eye/face protection: Use safety goggles with side protection

Respiratory protection: Necessary at aerosol or mist formation. Type: E (against acidic gases like sulphur dioxide or hydrogen chloride, colour code: Yellow). Usually no personal respiratory protection necessary.

Environmental exposure controls

Keep away from drains, surface and ground water.

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	liquid	colourless	characteristic, not determined	not determined	undetermined

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Component	Appearance form	Colour	Odour, odour threshold	pH value	Melting point
Wash buffer 10×	liquid	colourless	characteristic, not determined	not determined	undetermined
Positive Control	liquid	colourless	characteristic, not determined	not determined	undetermined
Negative Control	liquid	colourless	characteristic, not determined	not determined	undetermined
Conjugate	liquid	colourless	characteristic, not determined	not determined	undetermined
Substrate	liquid	colourless	characteristic, not determined	not determined	undetermined
Stop solution	liquid	colourless	characteristic, not determined	<2 (20°C)	undetermined

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	undetermined	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	non-combustible	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	fully miscible
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	none	23 hPa	not determined	fully miscible
Substrate	none	23 hPa	0.99972 g/cm ³	fully miscible
Stop solution	not determined	23 hPa	1.014 g/cm ³	fully miscible

Component	Viscosity	Solvent content	Solid content
Sample dilution buffer	not determined	organic solvents 0 % / water 100 %	none
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	not determined	organic solvents 0 % / water 97.5 %	99.6 %
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

Stop solution: Corrosive to metals (category 1)

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10 STABILITY AND REACTIVITY

10.1 Reactivity

Stop solution: Corrosive to metals (category 1).

10.2 Chemical stability

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Stop solution: violent reaction with strong alkali.

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials

Stop solution: different metals

10.6 Hazardous decomposition products

See section 5.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Component	CAS No	LD/LC values relevant for classification	value	species
Sulfuric acid	7664-93-9	LD ₅₀ (oral)	2,140 mg/kg	rat

Skin corrosion/ irritation

Causes skin irritation.

Serious eye damage/ irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitizer.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

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.

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12 ECOLOGICAL INFORMATION

12.1 Toxicity

Component	CAS No	Endpoint	Value	Species	Exposure time
Sulfuric acid	7664-93-9	EC50	> 100 mg/l	aquatic invertebrates	48 h
Sulfuric acid	7664-93-9	ErC50	> 100 mg/l	algae	72 h

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.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

After use, autoclave or incinerate per local, state, federal regulations. Treat as biohazardous material. Stop solution: This material and its container must be disposed of as hazardous waste. Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system/Do not empty into drains.

Uncleaned packaging

Disposal must be made according to official regulations. Only packagings which are approved (e.g. acc. to the Dangerous Goods Regulations) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

Relevant provisions relating to waste (Basel convention)

Properties of waste which render it hazardous

H8 Corrosives

14 TRANSPORT INFORMATION

14.1 UN number

ADR/ RID/ ADN: --

IMDG-Code: --

ICAO-TI: --

14.2 UN proper shipping name

None.

14.3 Transport hazard class(es)

None.

14.4 Packing group

None.

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14.5 Environmental hazards

None.

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 cargo is not intended to be carried in bulk.

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.

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.