

MATERIAL SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

MegaRSAT® BRUCELLA canis

Test-kit for the qualitative detection of antibodies against *Brucella canis* in serum of the dog.
Art. No. 550025RJ1 (25 tests)

Version 01/2023

TEST-KIT COMPONENTS

Contents

1. 2 glass slides with 6 antigen wells each, reusable
2. 0.75 ml Positive Control (PC, red cap)
3. 0.75 ml Negative Control (NC, green cap)
4. 2.5 ml Antigen (red cap)
5. 1.5 2-mercaptoethanol (yellow cap)
6. 25 stirring rods
7. 75 disposable plastic pipettes (20 µl)
8. 25 reagent tubes
9. 1 instructions for use

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

1.1 Product identifier

Trade name: MegaRSAT® BRUCELLA canis

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

Sector of use: IVD product

Product category: GIVD code of the complete kit: Bacteriology – Infectious immunology – 15.01.90.01

Application of the substance/the mixture: IVD.

1.3 Details of the supplier of the safety data sheet

Manufacturer/ Supplier:

MEGACOR Diagnostik GmbH, Lochauer Str. 2, A-6912 Hörbranz, Austria, info@megacor.at

1.4 Emergency telephone number: During normal opening times: +43 5573 85400

2 HAZARDOUS INGREDIENTS

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:  for 2-Mercaptoethanol (*)

Signal word: Warning

Hazard statements: H317 – May cause an allergic skin reaction. Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

(*) For detailed information check Material Safety Information Sheet for 2-Mercaptoethanol (can be ordered at info@megacor.at)

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3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Chemical characterization: Mixtures

The vials contain different solutions for the detection of antibodies against *Brucella canis*.

Description Positive Control:

The Positive Control contains canine antibodies against *Brucella canis*.

Description Negative Control:

The Negative Control does not contain canine antibodies against *Brucella canis*.

Description Antigen:

The Antigen is made of Latex particles coated with deactivated (killed) *Brucella canis* antigens.

Description 2-Mercaptoethanol:

The vial contains 50 mM 2-Mercaptoethanol. (*)

4 FIRST-AID MEASURES

4.1 Description of first aid measures

General information: If symptoms persist, call a physician.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Generally the product does not irritate the skin.

After eye contact: Rinse immediately opened eye for several minutes under running water.

After swallowing: If symptoms persist, consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

May cause allergy symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.

Symptoms of allergic reaction may include rash, itching, swelling and other symptoms.

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:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Safety goggles. Wear suitable respiratory equipment, boots and gloves. Avoid breathing vapours, mist or gas. Keep away from sources of ignition. No smoking.

6.2 Environmental precautions

No special measures required.

6.3 Methods and material for containment and cleaning up

Keep in suitable, closed containers for disposal. Sweep up spillage and collect in suitable container for disposal (use disinfectant if needed).

6.4 References 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.

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7 HANDLING AND STORAGE

7.1 **Precautions for safe handling:** Ensure adequate ventilation. Wear personal protective equipment. Avoid ingestion and inhalation. Do not get in eyes, on skin, or on clothing.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Wash hands before breaks and at the end of workday.

Information about fire and explosion protection: No special measures required.

7.2 **Conditions for safe storage, including any incompatibilities**

Storage: Keep vials tightly closed. Store at 2–8°C.

7.3 **Specific end use(s):** Use in laboratories.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data, see Section 7.

8.1 **Control parameters**

Ingredients with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

8.2 **Exposure controls**

Personal protective equipment:

General protective and hygienic measures: Wear gloves, lab coat. The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not required.

Protection of hands: 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 substance/the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration rates, 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 cannot 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.

Eye protection: Googles recommended.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1	Colour	N/A
9.2	Odour	N/A
9.3	Boiling Point	N/A
9.4	Evaporation Rate	N/A
9.5	Specific Gravity	N/A
9.6	Percent Volatile	N/A
9.7	Vapor Density	N/A
9.8	Vapor Pressure	N/A
9.9	Water Solubility	N/A

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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. Stable if stored under recommended storage conditions.

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

No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

11.1 Acute overexposure None

11.2 Sensitisation None

11.3 Chronic overexposure None

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: Not known to be hazardous to water.

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

After use, autoclave or incinerate per local, state, federal regulations. Treat as biohazardous material.

14. TRANSPORT INFORMATION

14.1 **UN-Number** N/A

14.2 **UN proper shipping name** N/A

14.3 **Transport hazard class(es)** N/A

14.4 **Packing group** N/A

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.

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15. REGULATORY INFORMATION

- 15.1 **Safety, health and environmental regulations / legislation specific for the substance of mixture Directive 2012/18/EU**
Named dangerous substances – ANNEX I None of the ingredients is listed.
- 15.2 **Chemical safety assessment A** Chemical Safety Assessment has not been carried out.
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MISCELLANEOUS INFORMATION

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