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Expert Opinion

on the efficacy of

MediSeptic Antiinfektionsmittel A50

against

Modified vaccinia virus Ankara (MVA)

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Akkreditiert nach DIN EN ISO/IEC 17025

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2020-07-09

The efficacy of the product **MediSeptic Antiinfektionsmittel A50** against Modified vaccinia virus Ankara was tested in a suspension test according to the European standard DIN EN 14476: 2019-10. In the amendment of this standard, Modified vaccinia virus Ankara is the new test virus for the claim “virucidal efficacy against enveloped viruses”. The effectiveness of the disinfectant was evaluated under clean conditions (0.3 g/l BSA) as interfering substance. **MediSeptic Antiinfektionsmittel A50** was tested as a 20.0%, 40.0% and 80.0% concentration. The exposure times were 30 and 60 seconds and 5 minutes.

In conclusion, the 80.0% concentration of the product MediSeptic Antiinfektionsmittel A50 is effective against the Modified vaccinia virus Ankara at room temperature under clean conditions (0.3 g/l BSA) as interfering substance with an application time of 30 seconds.

According to the Guidance on the Biocidal Products Regulation, Volume II, Parts B & C from April 2018, an efficacy against Modified vaccinia virus Ankara enable to claim an efficacy against all enveloped virus.

Moreover, Coronaviruses being included in the group of enveloped virus as described in Annex A of the EN 14476:2019-10, it can be concluded that MediSeptic Antiinfektionsmittel A50 is effective against Coronavirus SARS-CoV-2.

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CUSTOMER NUMBER
1895

DATE
August 10, 2020

REPORT 201450.V2

MEDISEPTIC ANTIINFEKTIONSMITTEL A50

BACTERICIDAL ACTIVITY

(EN 13727)

Purpose

The bactericidal activity of the hygienic handrub disinfectant **MediSeptic Antiinfektionsmittel A50** (MediSeptic AG, Schaan, Liechtenstein) should be evaluated in accordance with the European Standard **EN 13727 (2012+A2:2015)**.

This **version 02** of the report replaces the Hygiene Nord GmbH test report 201450.V1, English Version 01, dated August 06, 2020, and corrects the amounts of Povidone K15 and Calcium fluoride in the list of ingredients on Page 2 in accordance with the customer´s rectification. The **efficacy** claim remains unchanged.

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HANDELSREGISTER: AMTSGERICHT STRALSUND HRB 5168

Test Method

Testing is based on the European Standard EN 13727 (2012+A2:2015). Validation and control procedures are therefore carried out in accordance with that standard, too.

For the test, to a sample of the product **MediSeptic Antiinfektionsmittel A50** (diluted with water for injections, if necessary) is added to a suspension of test organisms in a solution of the interfering substance. The mixture is maintained at 20±1 °C for the required contact time. At the end of the contact time, an aliquot of 1 ml is taken; the microbicidal activity in this portion is immediately neutralized. Two 1 ml samples (per dilution step) of the resulting suspension are spread on at least 2 plates each. The number of surviving test organisms in the test mixture is calculated for each sample and the reduction is determined with respect to the corresponding test suspension N_0.

In the absence of a sufficient neutralizer for the reference strain *S. aureus* and in accordance with the EN 13727 procedure, samples had to be subjected to membrane filtration for neutralization. At the end of the contact time two 1 ml samples of that suspension are directly subjected to membrane filtration for final neutralization. In parallel, dilutions of that solution are prepared and treated similarly. The membranes are then transferred to nutrient plates for incubation.

The experimental conditions (control A), the non-toxicity of the neutralizer (control B) and the dilution-neutralization method or membrane filtration method (control C) are validated in accordance with the EN 13727. The test is performed under clean conditions (0.03 % albumin) using *S. aureus, E. hirae, P. aeruginosa* and *E. coli* as test-organisms. Results are presented in tables 1.1 – 4.2

Results [2]

In accordance with the EN 13727 (2012+A2:2015), the test product **MediSeptic Antiinfektionsmittel A50**, applied at a product concentration of **50 %**, appears to possess **bactericidal efficacy** ($\log_{10}$ RF ≥ 5) in **60 s** under clean conditions at 20±1 °C for the reference strains *S. aureus, E. hirae, P. aeruginosa* and *E. coli* (Tab. 1.1 – 4.2).

Results are considered validated in accordance with the requirements of the EN 13727 (2012+A2:2015).

Greifswald, August 10, 2020

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CUSTOMER NUMBER
1895

DATE
August 10, 2020

REPORT 201451.V2

MEDISEPTIC ANTIINFEKTIONSMITTEL A50

YEASTICIDAL ACTIVITY

(EN 13624)

Purpose

The yeasticidal activity of **MediSeptic Antiinfektionsmittel A50** (MediSeptic AG, Schaan, Liechtenstein) should be evaluated in accordance with the European Standard **EN 13624 (2013).**

This **version 02** of the report replaces the Hygiene Nord GmbH test report 201451.V1, English Version 01, dated August 06, 2020, and corrects the amounts of Povidone K15 and Calcium fluoride in the list of ingredients on Page 2 in accordance with the customer´s rectification. The efficacy claim remains unchanged.

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Test Method

Testing is based on the European Standard EN 13624 (2013). Validation and control procedures are therefore carried out in accordance with that standard, too.

For the test, to a sample of the product **MediSeptic Antiinfektionsmittel A50** (diluted with water for injections, if necessary) is added to a suspension of test organisms in a solution of the interfering substance. The mixture is maintained at 20±1 °C for the required contact time. At the end of the contact time, an aliquot of 1 ml is taken; the microbicidal activity in this portion is immediately neutralized. Two 1 ml samples (per dilution step) of the resulting suspension are spread on at least 2 plates each. The number of surviving test organisms in the test mixture is calculated for each sample and the reduction is determined with respect to the corresponding test suspension N_0.

In the absence of a sufficient neutralizer and in accordance with the EN 13624 procedure, samples had to be subjected to membrane filtration for neutralization. At the end of the contact time two 1 ml samples of that suspension are directly subjected to membrane filtration for final neutralization. In parallel, dilutions of that solution are prepared and treated similarly. The membranes are then transferred to nutrient plates for incubation.

The experimental conditions (control A), the non-toxicity of the neutralizer (control B) and the dilution-neutralization method (control C) are validated in accordance with the EN 13624. The test is performed under clean conditions (0.03 % albumin) using *C. albicans* as test-organism. Results are presented in table 1-3.

Results [2]

In accordance with the EN 13624 (2013), the test product **MediSeptic Antiinfektionsmittel A50**, when applied at a concentration of at least **80 %,** appears to possess **yeasticidal efficacy** ($\log_{10}$ RF $\geq$ 4) in **60 s** under clean conditions at 20±1 °C for the reference strain *C. albicans* (Tab. 3).

Results are considered validated in accordance with the requirements of the EN 13624 (2013).

Greifswald, August 10, 2020

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11.05.2020

Expert's Report - Evaluation of Antiinfectant A50 for hygienic hand rub according to EN 1500

We tested the product Antiinfectant A50, denoted below as test product (P), regarding its suitability for hygienic handrub based on the requirements of the European Standard EN 1500 (1997) "Chemical disinfectants and antiseptics – Hygienic handrub. Test method and requirements (phase 2/step2)".

1. Identification of the product (P) under evaluation

Test sample identification:	A50
Manufacturing date:	04.05.2020
Manufactured for:	MediSeptic AG
Test laboratory:	Institut für Laborwissenschaften, Hauptstrasse 140, A-8301 Lassnitzhöhe (Austria)
Test period:	06.05. – 07.05.2020
Product Description:	Colorless, clear liquid with aromatic smell
pH-value (concentrate):	2.71
Active ingredients in mg/l:	Water 985000 mg/L, Benzalkonium chloride1000 mg/L, Calcium fluoride 100 mg/L, Salicylic acid 2500 mg/L, Glycerin 9000 mg/L, PVP 2400 mg/L

2. Nutrient media and reagents

2.1. Water:
Aqua dest., sterile (BBraun PZN 1600469)

2.2. Nutrient medium:
Tryptic soybean agar; TSA (Carl Roth, Karlsruhe, Germany) containing desoxycholic acid-Na (Carl Roth, Karlsruhe, Germany)

2.3. Recovery and dilution fluid

Tryptic soy broth, TSB, Ph.Eur. (Carl Roth, Karlsruhe, Germany)

2.4. Neutralizers (ingredients/L):

30 ml Tween® 80 Ph.Eur. (polysorbate 80) (Carl Roth, Karlsruhe, Germany)
30 g saponin (Carl Roth, Karlsruhe, Germany)
1g L-histidine (Carl Roth, Karlsruhe, Germany)
1g L-cysteine (Carl Roth, Karlsruhe, Germany)

2.5. Potassic soft soap:

According to paragraph 5.4.6 of the standard; mass concentration 200 g/L

2.6. Reference handrub:

Propan-2-ol, 60% v/v, analytical grade

3. Test conditions

Product volume:	2x3 ml
Test concentration:	undiluted
Exposure time:	2x30s
Application frequency:	twice
Application mode:	standard handrub procedure according to annex A, reference disinfection procedure (R) according to paragraph 5.6.4.2 of the standard
Test organism:	Escherichia coli K12 (NCTC 10538)
Colony count:	$9.8x10^8$ (9.02 log) cfu/ml contamination suspension

4. Test results

The raw data from the tests with R and P are documented in tables 1 and 2, available upon request. These tables show colony counts expressed as colony forming units (cfu). The numbers used for further calculations are underlined. The numbers with asterisk indicate the use of the weighted mean value.
Table 3 demonstrates the calculated log values, i.e. the logarithms of the mean, and if required weighted counts per ml collection fluid, derived from the marked colony numbers. The log pre- and postvalues are listed by reference and test procedures for each subject.
The overall mean values obtained for the reference handrub procedure were

for the prevalues	7.01
for the postvalues	1.37
for the reduction factors	5.01

The corresponding values for the procedure with the test product were:

for the prevalues	7.04
for the postvalues	1.28
for the reduction factors	5.50

Results of 15 subjects were available. The overall means of the log prevalues for reference and test procedure were > 5.0. Log reduction factors < 3.0 did not occur. The requirements for acceptance of the test results are fulfilled.

Mean reduction factor of P was higher than of R, significance testing was performed using Wilcoxon paired side-ranks test (one-sided, p=0.01). Because the lower rank sum (2.5) is smaller than the tabulated value for 15 test subjects, the difference is significant ($p<0.05$).

5. Conclusion and expert's statement

The test product Antiinfectant A50 conforms to the requirements of the European Standard EN 1500 and is therefore suitable for hygienic hand disinfection. Antiinfectant A50 was significantly more effective than the reference alcohol.

Practical application: Dry hands should be rubbed for 30 seconds with 3ml of the undiluted product.

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