



ActiMaris®

+

 Natural Health Care

skin
mucous membrane
wounds

EN

Testing the microbicidal efficacy and security of ActiMaris®

National Institute of Public Health (SZÚ), Prague CZ

Centre for Epidemiology and Microbiology
National Reference Laboratory for Disinfection and Sterilization

2017 · 2018 · 2019



Objective

Determination of the effectiveness of ActiMaris® products according to the standards of ČSN EN ISO

→ **BACTERICIDES** ←
→ **VIRUCIDES** ←
→ **FUNGICIDES / LEVUROCIDES** ←
→ **SPORICIDES** ←

Tested products:



ActiMaris® *forte*
Wound Irrigation Solution



ActiMaris® *sensitive*
Wound Irrigation Solution



ActiMaris® Wound Gel

Tested for:

- Staphylococcus aureus
- Methicillin-resistant Staphylococcus aureus (St 55)
- Methicillin-resistant Staphylococcus aureus (St 56)
- Enterococcus hirae
- Pseudomonas aeruginosa
- Escherichia coli
- E. coli-Bakteriophage Φ x 174
- Candida albicans
- Aspergillus brasiliensis
- Bacillus subtilis

by standard:

- EN ISO 13727
- EN ISO 13727+A2
- EN ISO 13704
- EN ISO 13624
- EN ISO 1500
- EN ISO 10993-10



Confirmed antimicrobial efficacy!

ActiMaris® – Uniqueness

CONFIRMED

- BACTERICIDAL (including MRSA)
- VIRUCIDAL
- FUNGICIDAL / LEVUROCIDAL (mould, yeast)
- SPORICIDAL

ActiMaris® also meets the requirements of hygienic hand and skin disinfection according to EN ISO 1500.

Tested by SZÚ Prague, 9/2017, 12/2018, 3/2019



ActiMaris® is the only medical device for moist treatment that has been proven to eliminate the following groups of microorganisms very quickly (under < 1 minute) and very effectively ($> 5 \log_{10}$):

- BACTERIA (including MRSA)
- VIRUSES
- YEASTS
- MOULDS
- BACTERIA SPORES

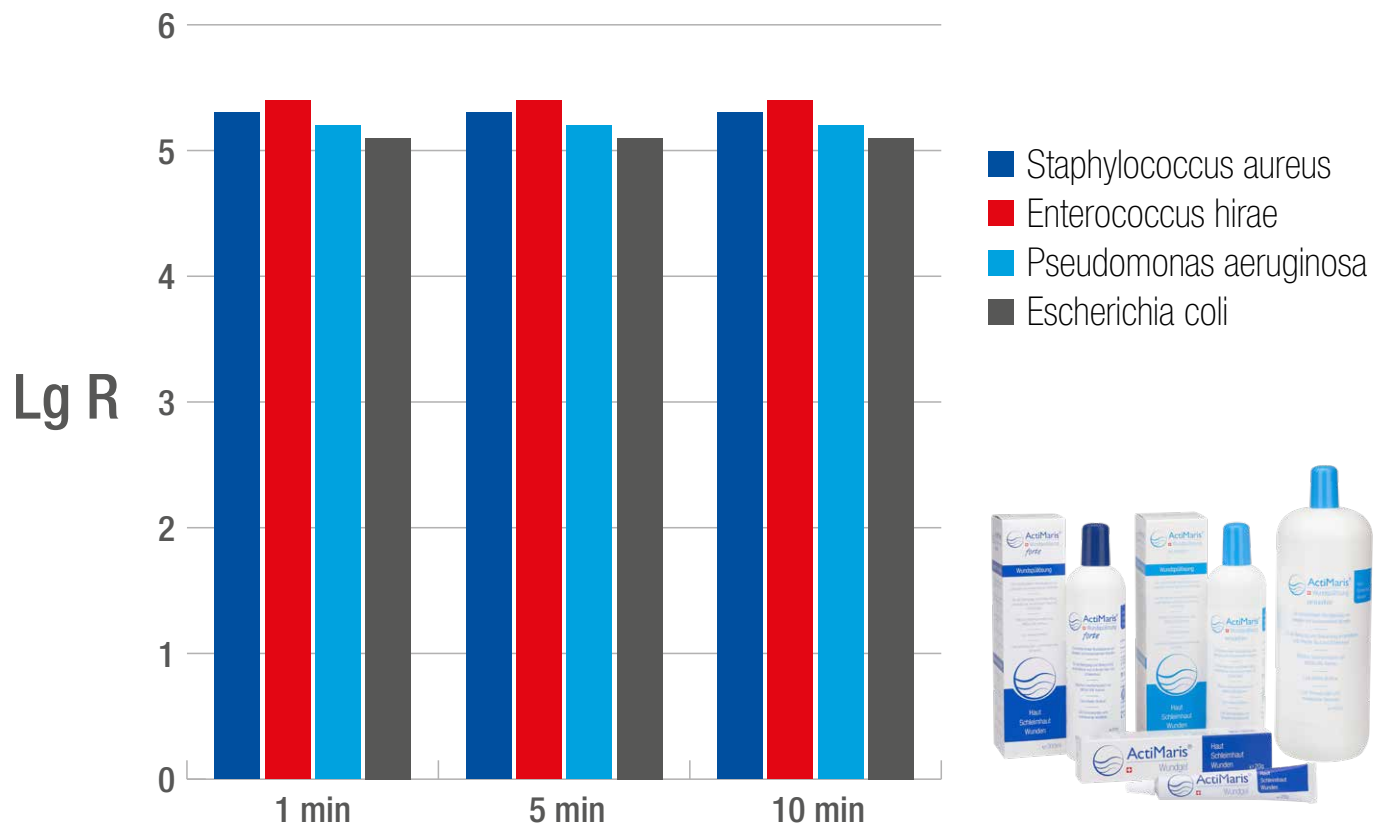


ActiMaris® destroys the broadest spectrum of pathogens of all antimicrobial medical devices available on the wound market.

Source: Results of the microbicide efficacy tests of SZÚ Prague, 9/2017, 12/2018, 3/2019

Bactericidal efficacy

of ActiMaris® products



ActiMaris® Forte, Sensitive und wound gel show a **significant bactericidal effect** even after standard dilution to 97% at exposure times of **1, 5 and 10 minutes**.

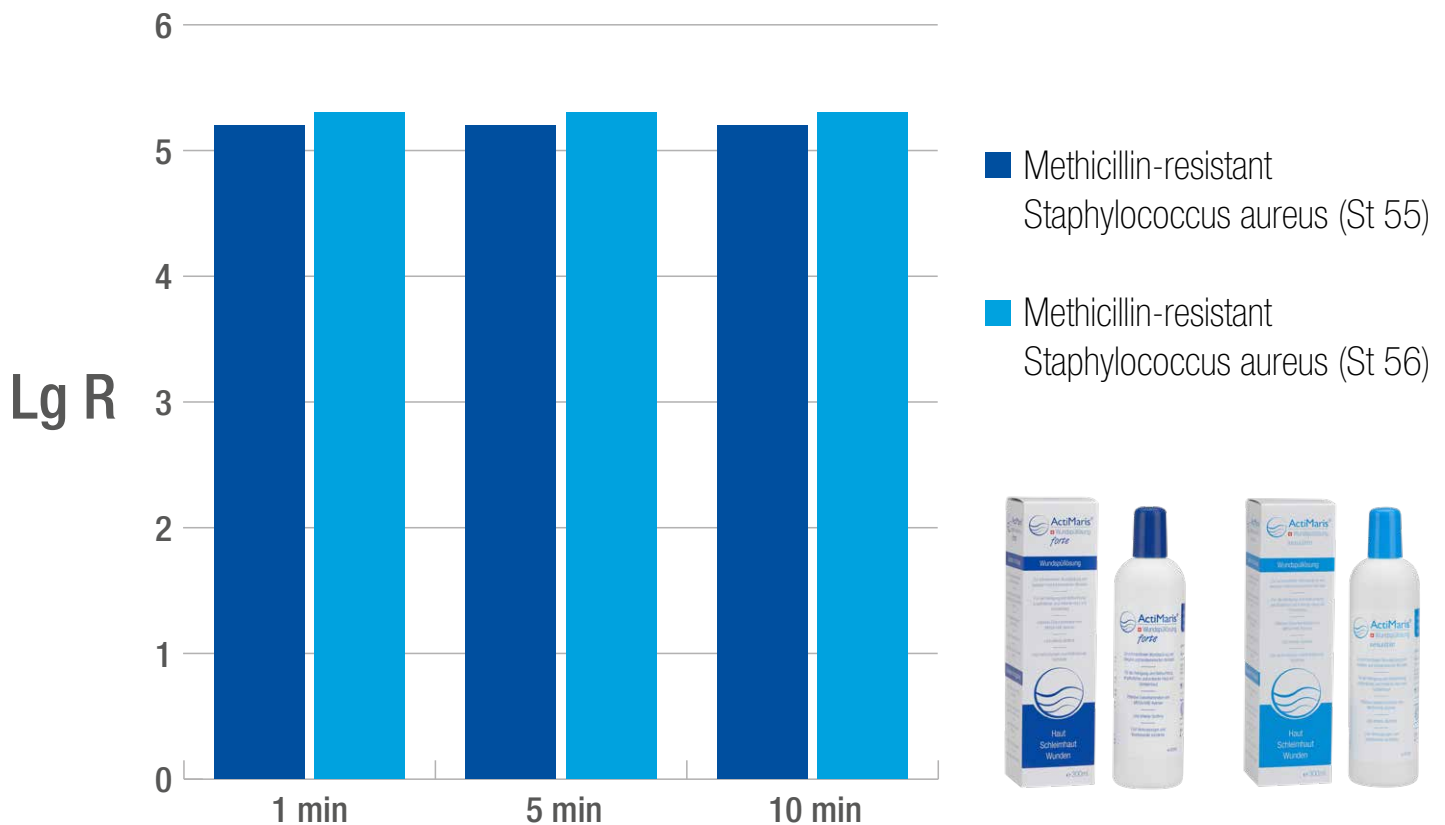


The number of microorganisms was reduced by $> 5 \log_{10}$ within 1 minute, which corresponds to a bactericidal efficacy according to standard norms of ČSN EN ISO 13727.

Tested by SZÚ Prague, 9/2017

MRSA – Bactericidal efficacy

of ActiMaris® *forte* and *sensitive*



ActiMaris® Forte and Sensitive wound irrigation solutions show a bactericidal effect on MRSA strains after dilution to 97% according to the standard after exposure times of 1, 5 and 10 minutes.

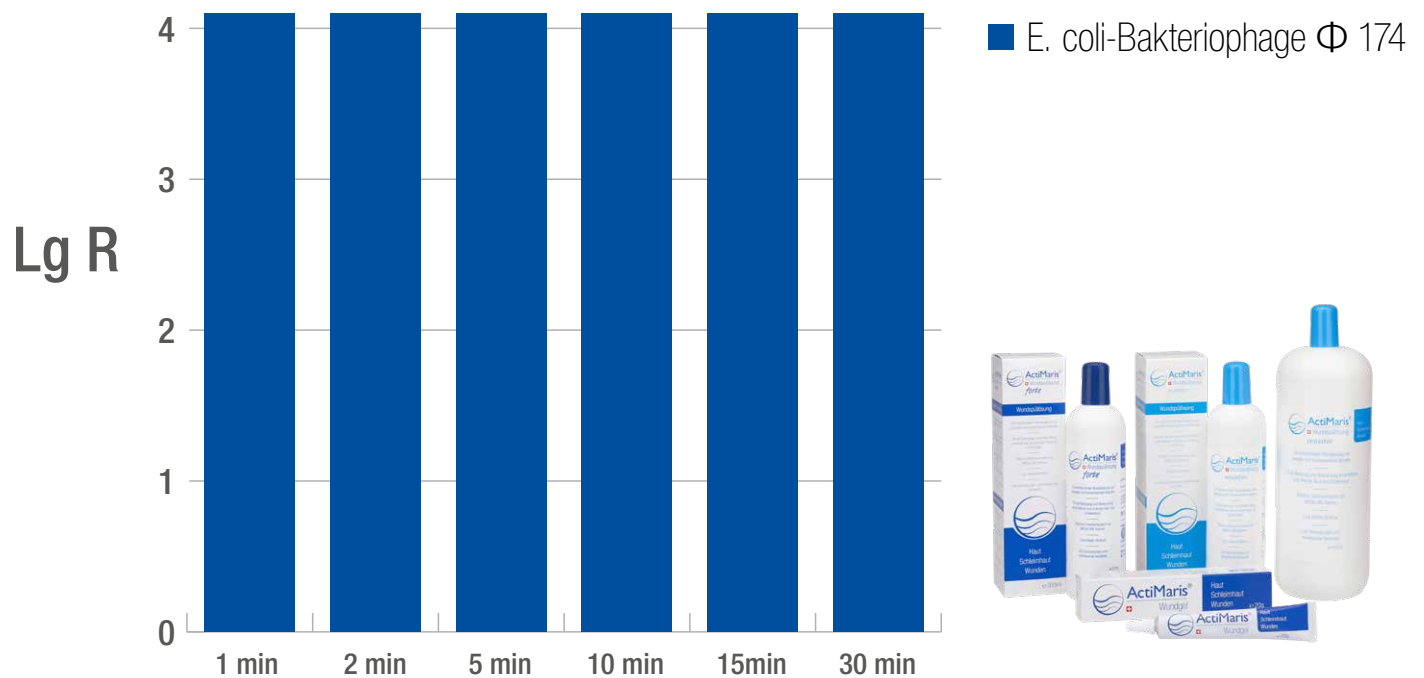


The number of microorganisms was reduced by $> 5 \log_{10}$ within 1 minute, which corresponds to a bactericidal efficacy according to standard norms of ČSN EN ISO 13727+A2.

Tested by SZÚ Prague, 12/2018

Virucidal efficacy

of ActiMaris® products



ActiMaris® Forte, Sensitive and wound gel show **virucidal efficacy** at 100% concentration over a treatment period of **1, 2, 5, 10, 15 and 30 minutes**.

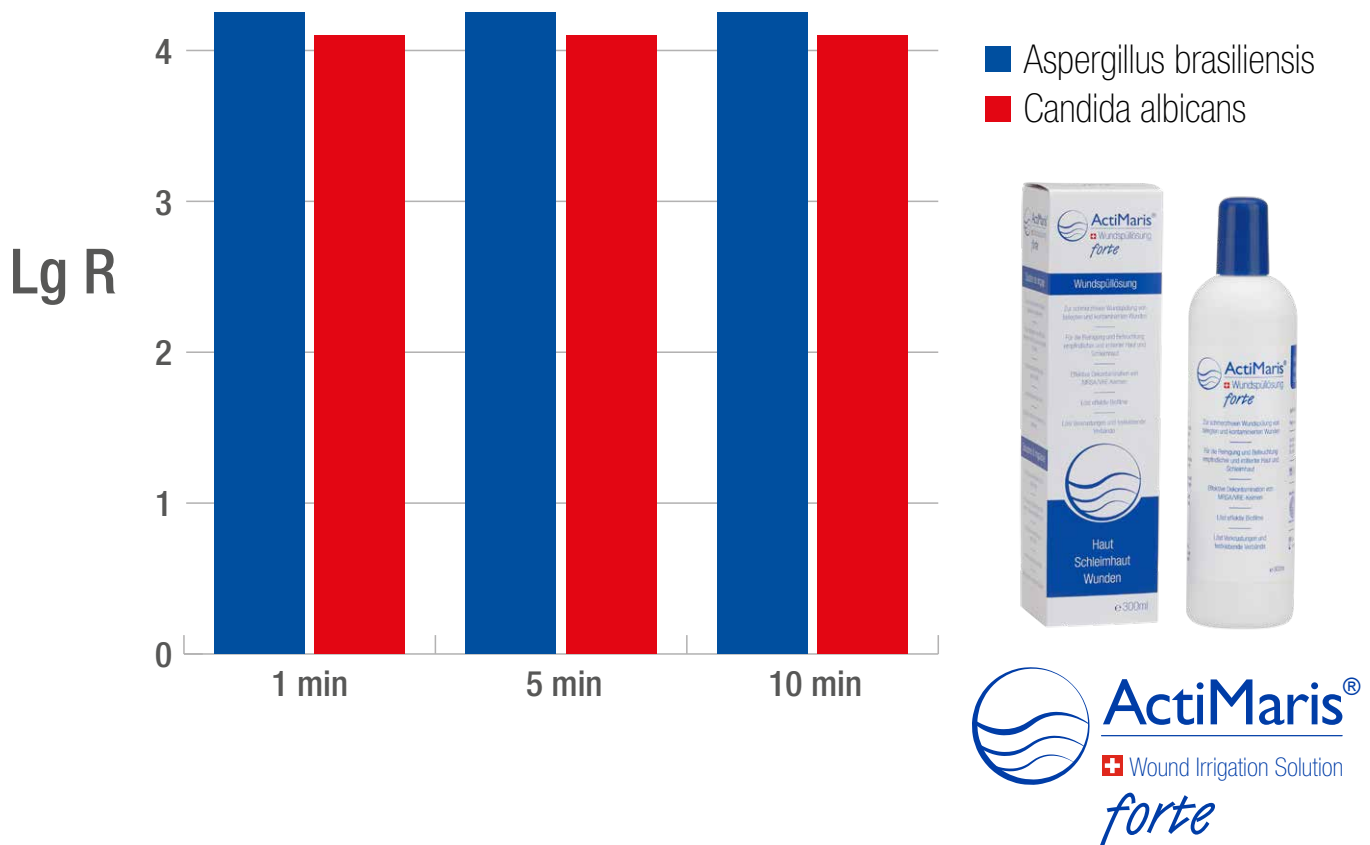


The number of CFU (colony forming unit) decreased by **> 4 log₁₀** within 1 minute, which corresponds to a virucidal efficacy according to standard norms of ČSN EN ISO 13727.

Tested by SZÚ Prague, 9/2017

Fungicidal and levurocidal efficacy

of ActiMaris® forte



Even after dilution to 97% ActiMaris® Forte wound irrigation solution shows **fungicidal and levurocidal efficacy** on both yeast and mould fungi for **1, 5 and 10 minutes**.

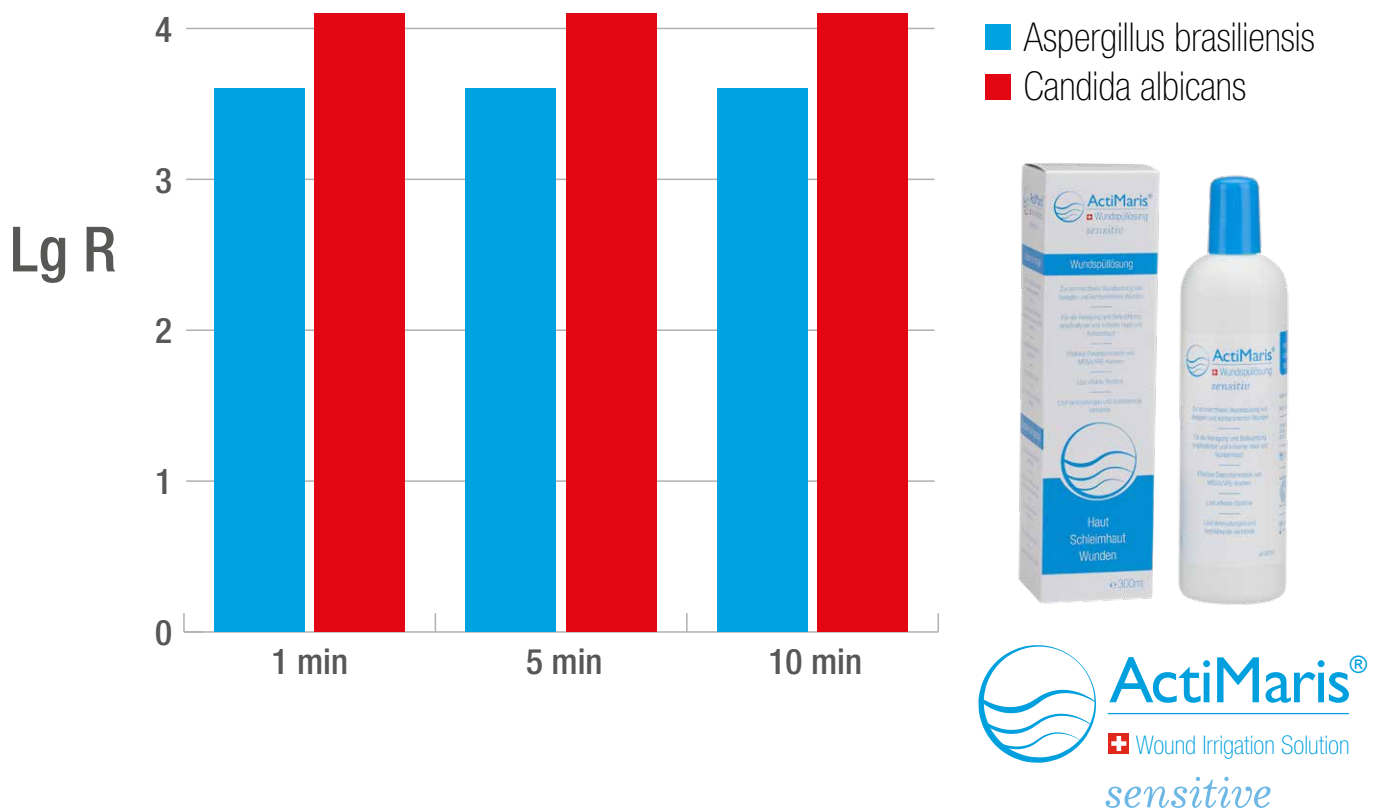


The number of microorganisms was reduced by $> 4 \log_{10}$ within 1 minute, which corresponds to a fungicidal and levurocidal efficacy according to standard norms of ČSN EN ISO 13624.

Tested by SZÚ Prague, 9/2017

Fungicidal and levurocidal efficacy

of ActiMaris® sensitive



When ActiMaris® Sensitive wound irrigation solutions are diluted to a standard of 97%, it shows **fungicidal and levurocidal efficacy** after exposure times of **1, 5 and 10 minutes (yeasts)** and **10 minutes (molds)**.

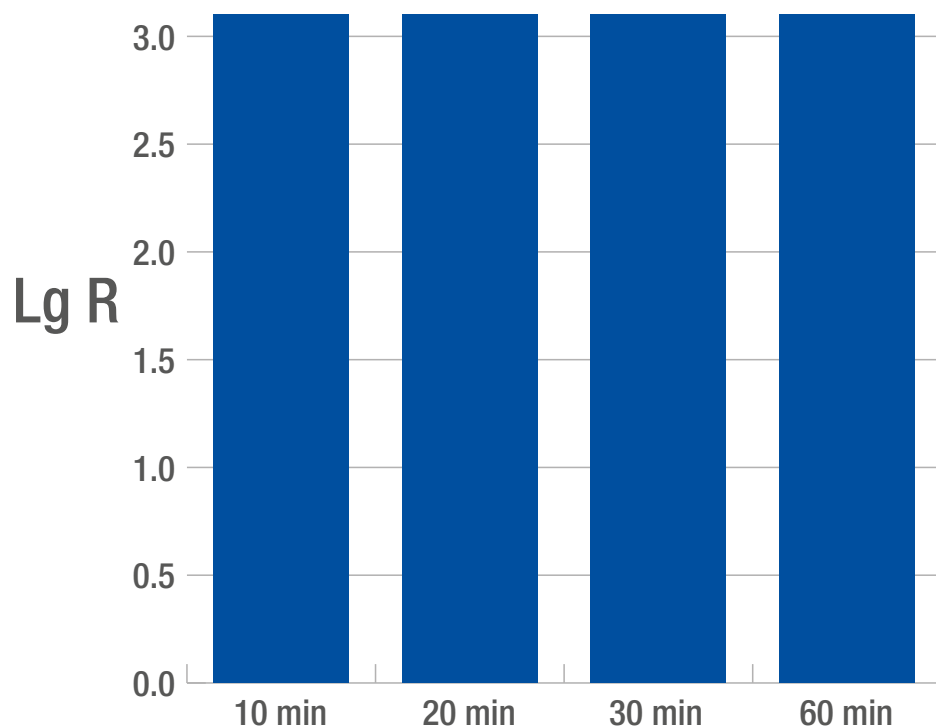


The number of microorganisms was reduced by $> 3 \log_{10}$ and $> 4 \log_{10}$ within 1 minute, which corresponds to a fungicidal and levurocidal efficacy according to standard norms of ČSN EN ISO 13624.

Tested by SZÚ Prague, 12/2018

Sporicidal efficacy

of ActiMaris® forte



■ Bacillus subtilis



ActiMaris® Forte wound irrigation solution, when diluted to 97%, shows **effective sporicidal efficacy** over 10, 20, 30 and 60 minutes.

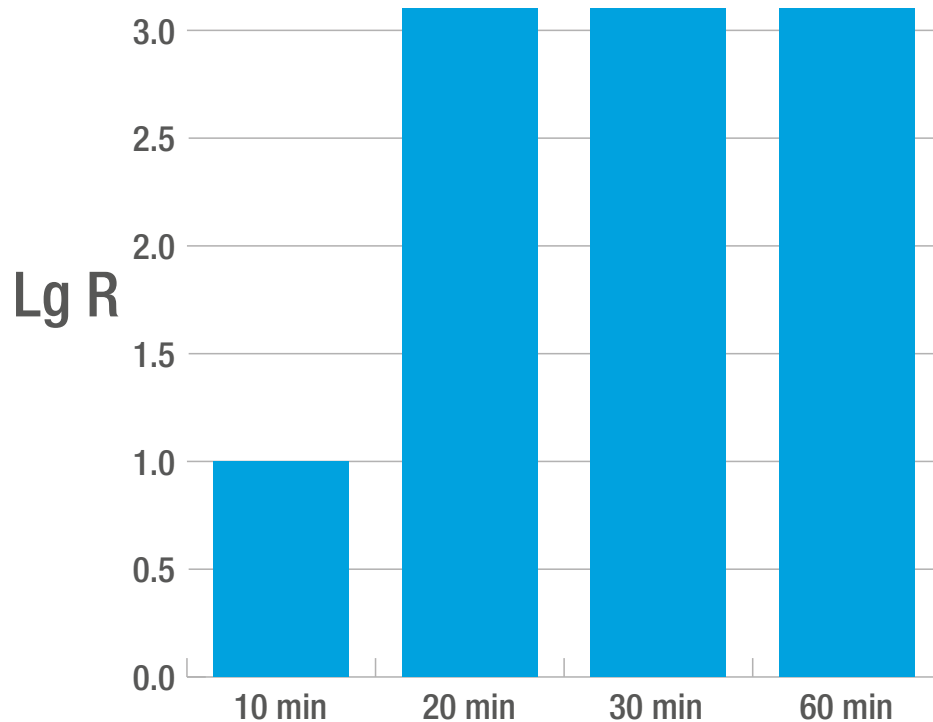


The number of bacterial spores was reduced by $> 3 \log_{10}$, which corresponds to a sporicidal efficacy according to standard norms of ČSN EN ISO 13704.

Tested by SZÚ Prague, 3/2019

Sporicidal efficacy

of ActiMaris® sensitive



■ Bacillus subtilis



 **ActiMaris®**
Wound Irrigation Solution
sensitive



ActiMaris® Sensitive wound irrigation solution, when diluted to 97%, shows **sporicidal efficacy** over 20, 30 and 60 minutes.



The number of bacterial spores was reduced by $> 3 \log_{10}$, which corresponds to a sporicidal efficacy according to standard norms of ČSN EN ISO 13704.

Tested by SZÚ Prague, 3/2019

Skin irritation and sensitization testing

of ActiMaris® products

National Institute of Public Health (SZÚ), Prague CZ

Center of laboratory activities

Toxicological laboratory

November 2017

DETERMINATION OF SKIN IRRITATION AND SENSITIZATION FOR HUMANS (90 PERSONS)

as a part of the biocompatibility testing

Tests for irritation and sensitivity according to ČSN EN ISO 10993-10:

Part 10: Articles 1, 2, 3, 4, 5, 6.2, 6.3, 6.4, 6.5, 7.5, Annex A, B.1, B.2, C, E, F

Tested products:



ActiMaris® forte
Wound Irrigation Solution



ActiMaris® sensitive
Wound Irrigation Solution



ActiMaris® Wound Gel



Tested by SZÚ Prague, 11/2017

Conclusion: Test for skin irritation and sensitization

with ActiMaris® products



ActiMaris® wound gel does not irritate the skin and does not cause any adverse skin reactions.



ActiMaris® Forte wound irrigation solution does not irritate the skin and does not cause irritation or sensitization of the skin.



ActiMaris® Sensitive wound irrigation solution shows in the EN ISO 10993-10 test no irritation and no sensitization of the skin and mucous membrane. It is very well tolerated by sensitive skin (also by children).



The ratio between the cytotoxicity in vitro (EN ISO 10993-5) and the antimicrobial effect (EN ISO 13727) shows an excellent balance and good biocompatibility.

Tested by SZÚ Prague, 11/2017

Conclusions:

Test results of the ActiMaris® products in
National Institute of Public Health (SZÚ), Prague CZ



ActiMaris® offers a broad and high antimicrobial spectrum with fast effect (< 1 minute) against all tested common pathogens.

Proven bactericidal (including MRSA), virucidal, fungicidal, levurocidal and sporicidal effect.



ActiMaris® is not toxic for healthy tissue, does not irritate and does not cause adverse skin reactions. ActiMaris® has a very good biocompatibility index in vitro and in vivo.



ActiMaris® products are suitable for short- and long-term application.



ActiMaris® products meet the hygienic requirements for hand and skin disinfection according to EN 1500 (tested in vivo).

Tested according to standards:

- EN ISO 13727
- EN ISO 13727+A2
- EN ISO 13704
- EN ISO 13624
- EN ISO 1500
- EN ISO 10993-10



Tested by SZÚ Prague, 2017 · 2018 · 2019

For further information
please visit our website.
www.ActiMaris.com

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natural medical solutions

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