

Dr. Schumacher GmbH

Am Roggenfeld 3

34323 Malsfeld

Deutschland / Germany

DATUM / DATE
02.10.2013 / Oktober 02, 2013

GUTACHTERLICHE STELLUNGNAHME / *EXPERT'S REPORT*
- ULTRASOL ACTIVE -

Von Juni bis August 2013 wurden durch die Hygiene Nord GmbH mit dem Prüfmuster **Ultrasol active** (Rezepturbezeichnung **PA 4525 OC**), einem Produkt zur Flächendesinfektion der Firma Dr. Schumacher GmbH, Malsfeld, Deutschland, die im Folgenden aufgeführten Untersuchungen gemäß der EN 13727 (2012/2013), der prEN 13624 (2010) und der EN 14348 (2005) durchgeführt:

*The efficacy of the surface disinfectant **Ultrasol active** (product formulation: **PA 4525 OC**), manufactured by Dr. Schumacher GmbH, Malsfeld, Germany, was evaluated by the testing laboratory Hygiene Nord GmbH, Greifswald, Germany. The following tests were performed between the months of June and August 2013 in accordance with the EN 13727 (2012/2013), the prEN 13624 (2010) and the EN 14348 (2005):*

1. Im **quantitativen Suspensionsversuch** wurde die bakterizide, levurozide, fungizide und tuberkulozide Wirksamkeit des Prüfmusters **Ultrasol active** unter hoher Belastung (0,3 % Albumin + 0,3 % Schaferythrozyten) bestimmt. Die Versuchsdurchführung und die Ergebnisse sind in den Prüfberichten A 13113-2 und A 13113-3 der Hygiene Nord GmbH vom 26.08.2013 enthalten.

*The bactericidal, yeasticidal, fungicidal and tuberculocidal efficacy of **Ultrasol active** was evaluated in **quantitative suspension tests** under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes). Results are presented in the Hygiene Nord GmbH test reports A 13113-2 and A 13113-3 (August 26, 2013).*

ZUSAMMENFASSUNG / SUMMARY

Nach Bewertung der Ergebnisse kann festgestellt werden, dass das Prüfprodukt **Ultrasol active** den Anforderungen der EN 13727 (2012/2013), der prEN 13624 (2010) und der EN 14348 (2005) genügt, da folgende Wirkungen beobachtet wurden:

*Upon evaluation of the test results it can be concluded that **Ultrasol active** complies with the requirements of the EN 13727 (2012/2013), the prEN 13624 (2010) and the EN 14348 (2005) as follows:*

bakterizide, levurozide, fungizide und tuberkulozide Wirksamkeit in den *in vitro* - Tests: In den **quantitativen Suspensionstests** unter hoher Belastung wurden die Prüfspezies *P. aeruginosa*, *E. hirae*, *S. aureus*, *S. aureus* (Bakterizidie, RF \geq 5 log) und *C. albicans* (Levurozidie, RF \geq 4 log) bei den Konzentration/Zeit-Relationen 1% / 1 min und 0,5% / 2 min in einem ausreichenden Maße inaktiviert. Die Prüfspezies *A. brasiliensis* (Fungizidie, inkl. *C. albicans*, RF \geq 4 log) wurde bei der Konzentration/Zeit-Relation 1% / 60 min und die Prüfspezies *M. terrae* (Tuberkulozidie, RF \geq 4 log) bei der Konzentration/Zeit-Relation 1% / 60 min in einem ausreichenden Maße inaktiviert.

*Bactericidal, yeasticidal, fungicidal and tuberculocidal activity in the in vitro tests: In the **quantitative suspension tests** under dirty conditions, the product possesses bactericidal (RF \geq 5 log) and yeasticidal (RF \geq 4 log) activity against the test organisms *P. aeruginosa*, *E. hirae*, *S. aureus* and *C. albicans*, respectively, within a contact time of 1 min at a product concentration of 1% and within a contact time of 2 min at a product concentration of 0.5%. The product possesses fungicidal activity (RF \geq 4 log) against the test organism *A. brasiliensis* (also incl. *C. albicans*) at the concentration/contact time – relation, 1% / 60 min. The product also possesses tuberculocidal activity (RF \geq 4 log) against the test organism *M. terrae* at the concentration/contact time – relation 1% / 60 min.*

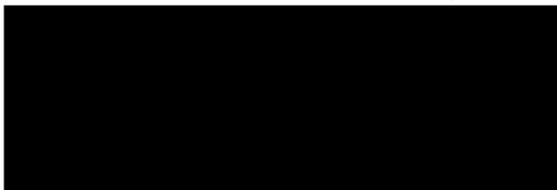
Die Wirksamkeit von **Ultrasol active** auf Basis der EN 13727, prEN 13624 und EN 14348 kann damit wie folgt zusammengefasst werden:

*With regard to the EN 13727, prEN 13624 and EN 14348, the efficacy of **Ultrasol active** can therefore be summarized as follows:*

Ultrasol active:
 (hohe Belastung / *dirty conditions*)

Bakterizidie, Levurozidie: <i>Bactericidal, yeasticidal efficacy</i>	Fungizidie: <i>Fungicidal efficacy:</i>	Tuberkulozidie: <i>Tuberculocidal efficacy:</i>
1% / 1 min 0.5% / 2 min		
	1% / 60 min	1% / 60 min

Greifswald, 02.10.2013 / Oktober 02, 2013



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2016-09-30

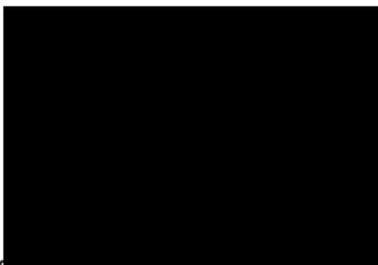
Ultrazol active
EN 14348
Tuberkulozide Wirkung - Phase 2, Stufe 1
Tuberculocidal activity - Phase 2, step 1

**GUTACHTERLICHE STELLUNGNAHME /
EXPERT OPINION**

Nach Prüfung der tuberkuloziden Wirksamkeit des Desinfektionsmittels **Ultrazol active** gebe ich die nachfolgende Beurteilung der Resultate des Prüfberichtes SN 20419.1 vom 30.09.2016. / *After testing the tuberculocidal efficacy of the disinfectant **Ultrazol active** I hereby issue the following evaluation of the results out of the test report SN 20419.1 dated 2016-09-30:*

Gemäß EN 14348 weist die Charge 6476217546 des Produktes **Ultrazol active** unter niedriger und hoher Belastung bei 20°C nach 15 Minuten bei Verdünnung auf 2.0% (m/v) eine tuberkulozide Wirkung gegen den Testkeim *Mycobacterium terrae* auf.

*According to EN 14348, the batch 6476217546 of the product **Ultrazol active** shows a tuberculocidal activity under clean and dirty conditions at 20°C in 15 minutes when diluted at 2.0% (m/v) against the test strain *Mycobacterium terrae*.*



Prof. Dr. med. H.-P. Werner

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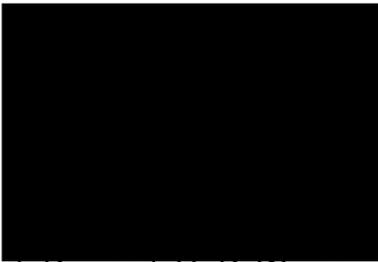
2016-12-16

Ultrasol® active
EN 16615 (2015)
4-field-test - bactericidal and yeasticidal activity
(Phase 2, step 2)

EXPERT OPINION

After testing the bactericidal efficacy of the disinfectant **Ultrasol® active** in combination with reference wipe I hereby issue the following evaluation of the results out of the test report dated 2016-04-18 (SN 19683.1; SN 19700).

According to EN 16615 (2015), the batch 5126219139 of the product **Ultrasol® active** in combination with the reference wipe shows a bactericidal activity at room temperature under clean conditions when diluted at 1.0% in 5 minutes and 0.5% in 15 minutes as well as under dirty conditions when diluted at 1.0% in 30 minutes and 0.5% in 60 minutes against the test strains *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 and *Pseudomonas aeruginosa* ATCC 15442 and a yeasticidal activity against *Candida albicans* ATCC 10231.



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2020-02-28

Ultrasol active
EN 17126 (2018)
Sporicidal activity

EXPERT OPINION

After testing the disinfectant **Ultrasol active** according to EN 17126 (2018) I give the following statement based on the results from the test laboratory HygCen Germany GmbH out of the test report dated 2019-12-18 (PB 2019-1942, 2019-1944, SN 28111):

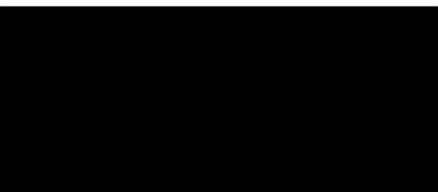
According to EN 17126, the product Ultrasol active shows a sporicidal activity ($\geq 4\lg$ reduction) at 20°C under:
clean and dirty conditions:

- 2%, 1.5% = 5, 15 minutes
- 2%, 1.5%, 1% = 30, 60 minutes

as well as under clean condition:

- 0.5% = 30, 60 minutes

for spores of the referenced test strain *Clostridioides difficile* R027.



Dr. med. univ. S. Werner

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2017-11-20

FD-255

Virucidal efficacy of FD-255 according to the quantitative Suspensionstest EN 14476:2016/prA2:2016

J U D G E M E N T

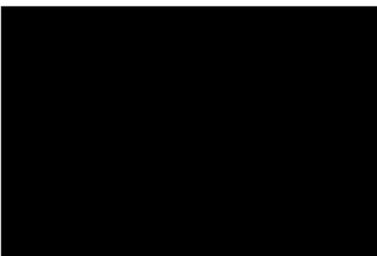
The testing of the disinfectant **FD-255** of the company Dr. Schumacher GmbH was carried out according to EN 14476:2016/prA2:2016. The test was done with the testviruses **Poliovirus Type 1**, **Adenovirus Type 5** and **Murine Norovirus (MNV)** at clean and dirty conditions (testreport SN 23986 I of 2017-11-20).

The following results could be determined for the individual test viruses:

Poliovirus:	2.0% / 30 min
Adenovirus:	0.5% / 15 min
Murines Norovirus:	1.0% / 15 min

Therefore, a virucidal efficacy of the **2%** disinfectant **FD-255** according to EN 14476 against Poliovirus Type 1, Adenovirus Type 5 and Murine Norovirus can be confirmed after **30 min** under clean and dirty conditions.

Therefore under the same conditions of use can be based upon compliance with the afore mentioned application parameters a virucidal efficacy, which also includes enveloped pathogens such as HIV, HBV, HCV, Influenza Viruses (Annex A).



Prof. Dr. med. H.-P. Werner

We protect
your health.



Dr. Schumacher

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10 July 2018 FM/cs

2018-311

Compatibility confirmation for several Dr. Schumacher products

Dear Ms. Mickeviciene,

With reference to your inquiry dated 9th July 2018 we can provide following information regarding your questions:

Question 1: Is *ULTRASOL® ACTIVE* suitable for disinfection and cleaning in newborn departments and/or of anesthetic equipment?

We herewith confirm that *ULTRASOL® ACTIVE* is suitable for disinfection und cleaning of medical equipment in newborn departments.

According to MDD *ULTRASOL® ACTIVE* is suitable for disinfection and cleaning of non-invasive medical devices which includes anesthesia Materials.

Question 2: Can *PERFEKTAN® ACTIVE* be used for reprocessing of flexible and rigid endoscopes of the manufacturers Olympus, K. Storz and Fujinon?

From our experience we can confirm that *PERFEKTAN® ACTIVE* is suitable for reprocessing of rigid and flexible endoscopes from the above mentioned manufacturers.

We hope this Information is helpful.

Kind regards
Dr. Schumacher GmbH

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