

SANUSLIFE INTERNATIONAL GmbH / Srl
Luigi-Negrelli-Straße 13/C

39100 Bozen
Italy

Bad Bocklet, 11 May 2018

Test report (Version 01)

Sample: ECAIA +

L+S-No.: 170817-0028-001

Order: Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas according to EN 13697:2015

(Order of 11.08.2017)

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.

The test results apply solely to the designated samples.

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- Test report (Version 01) on ECAIA + (Quantitative surface test according to EN 13697) -
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Labor LS SE & Co. KG
Manglerweg 4, 5, 6
97082 Bad Bocklet
AG für Wirtschaftsprüfung

Dr. Ingrid Heide
Labor LS SE & Co. KG

Dr. Ingrid Heide
Labor LS SE Verwaltungsgesellschaft
Manglerweg 4, 5, 6
97082 Bad Bocklet
AG für Wirtschaftsprüfung

Dr. Peter Lörcher
Labor LS SE & Co. KG
Manglerweg 4, 5, 6
97082 Bad Bocklet
AG für Wirtschaftsprüfung

Dr. Peter Lörcher
Labor LS SE & Co. KG

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Labor LS SE & Co. KG

Dr. Peter Lörcher
Labor LS SE & Co. KG

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Labor LS SE & Co. KG

Material and Method

Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas according to EN 13697:2015 (Juni 2015)

1. Laboratory Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6

D - 97708 Bad Bocklet

2. Identification of the sample

Product name: ECAIA +
Manufacturer: SANUSLIFE INTERNATIONAL GmbH / Srl
Active substances:
(per 100 g product) Sodium hypochlorite CAS: 7681-52-9 EG-No. 231-668-3
0.07 – 0.13 g/100g
Appearance of the product: liquid, clear, colourless
pH- value (100%): 8.76
Delivery date: 16.08.2017
Storage conditions: room temperature

3. Test conditions

Period of testing: 30.08.2017 - 19.10.2017
Test strains: *Staphylococcus (S.) aureus* ATCC 6538
Escherichia (E.) coli ATCC 10536
Enterococcus (Ec.) hirae ATCC 10541
Pseudomonas (P.) aeruginosa ATCC 15442
Candida (C.) albicans ATCC 10231
Aspergillus (A.) brasiliensis – spores ATCC 16404
Bacillus (B.) subtilis – spores ATCC 6633
Test concentration: undiluted
Contact times: 30 sec (*E. coli*, *Ec. hirae*, *C. albicans*)
60 sec (*S. aureus*, *P. aeruginosa*)
5 min (*A. brasiliensis* – spores)
60 min (*B. subtilis* – spores)
Organic loading: 0.03% albumin

Test temperature:	18°C – 25°C
Test surface:	stainless steel
Counting method:	surface method
Incubation period:	48 h, 36°C ± 1°C (veg. bacteria, bact. spores) 48 h, 30°C ± 1°C (<i>C. albicans</i>) 4 - 5 days, 30°C ± 1°C (<i>A. brasiliensis</i>)

4. Test method and its validation

Test method:	Dilution-neutralisation
Inactivation combination:	10% Tween 80 + 3.0% lecithin + 0.3% histidine + 0.5% sodium-thiosulfat in casein-soy-broth

The results of the validation tests proved the validity of the method in all cases.

5. Test results

The results are stated in tables A (summary table) and 1 – 4.

Table A: Summary of the log reductions of the quantitative surface tests according to EN 13697

Product: ECAIA + Concentration: undiluted Contact time: 30 sec Organic loading: 0.03% albumin Test temperature: 18°C - 25°C	
Test strain	log-reduction
<i>E. coli</i>	> 6.49
<i>Ec. hirae</i>	> 6.74
<i>C. albicans</i>	3.04
Contact time: 60 sec	
Test strain	log-reduction
<i>S. aureus</i>	> 6.67
<i>P. aeruginosa</i>	> 6.85
Contact time: 5 min	
Test strain	log-reduction
<i>A. brasiliensis</i> - spores	> 5.68
Contact time: 60 min	
Test strain	log-reduction
<i>B. subtilis</i> - spores	> 5.75

6. Conclusion

In accordance with the requirements of EN 13697 the product **ECAIA +** showed the required microbial reduction of ≥ 4 log with reference to the test strains *S. aureus*, *E. coli*, *Ec. hirae* and *P. aeruginosa* resp. the required microbial reduction of ≥ 3 log with reference to the test strains *C. albicans* and *A. brasiliensis* at the following concentration-time relations. For the sporicidal activity with reference to the test strain *B. subtilis* a microbial reduction of ≥ 3 log was defined.

Bactericidal activity under clean conditions (0.03% albumin):
undiluted 60 sec contact time

Yeasticidal activity under clean conditions (0.03% albumin):
undiluted 30 sec contact time

Fungicidal activity under clean conditions (0.03% albumin):
undiluted 5 min contact time

Sporicidal activity under clean conditions (0.03% albumin):
undiluted 60 min contact time

The controls demonstrated the validity of the testing method.

11. MAI 2018


Dipl-Biol Anastasija Schlicht
- Manager Business Unit Services -


11. MAI 2018 
Anna-Lena Kirchner
- Laboratory Technician -

Table 1: Quantitative surface test according to EN 13697

Product: ECAIA +

Contact time: 30 seconds

Organic loading: 0.03% albumin

Test temperature: 18°C - 25°C

Test surface: Stainless steel

Test strain	Test suspension	Water Control N_c	Concentration: undiluted
<i>E. coli</i> ATCC 10536	10 ⁻⁶ : > 330 / > 330 10 ⁻⁷ : 34 / 38 N: 6.95 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 34 / 44 10 ⁻⁵ : 6 / 2 10 ⁻⁶ : 1 / 1 N_c : 6.59 log N_{is} : > 330	10 ⁰ : 0 / 0 10 ⁻¹ : 0 / 0 10 ⁻² : 0 / 0 N_d : < 0.10 log N_{is} : 0 ME: > 6.49 log
<i>Ec. hirae</i> ATCC 10541	10 ⁻⁶ : > 330 / > 330 10 ⁻⁷ : 43 / 36 N: 6.99 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 73 / 66 10 ⁻⁵ : 12 / 9 10 ⁻⁶ : 2 / 2 N_c : 6.84 log N_{is} : > 330	10 ⁰ : 0 / 0 10 ⁻¹ : 0 / 0 10 ⁻² : 0 / 0 N_d : < 0.10 log N_{is} : 0 ME: > 6.74 log
<i>C. albicans</i> ATCC 10231	10 ⁻⁵ : 182 / 182 10 ⁻⁶ : 28 / 30 N: 5.68 log	10 ⁻² : > 330 / > 330 10 ⁻³ : 57 / 54 10 ⁻⁴ : 10 / 5 10 ⁻⁵ : 0 / 0 N_c : 5.74 log N_{is} : > 330	10 ⁰ : 44 / 56 10 ⁻¹ : 6 / 3 10 ⁻² : 0 / 0 N_d : 2.70 log N_{is} : 15 ME: 3.04 log

Validation to table 1:

Test strain	Test suspension	Validation N_c	Validation N_r
<i>E coli</i> ATCC 10536	10 ⁻⁶ : > 330 / > 330 10 ⁻⁷ : 34 / 38 N: 6.95 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 40 / 38 10 ⁻⁵ : 4 / 4 N_c : 6.59 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 36 / 56 10 ⁻⁵ : 8 / 8 N_r : 6.66 log
<i>Ec. hirae</i> ATCC 10541	10 ⁻⁶ : > 330 / > 330 10 ⁻⁷ : 36 / 43 N: 6.99 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 64 / 34 10 ⁻⁵ : 8 / 2 N_c : 6.69 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 40 / 34 10 ⁻⁵ : 5 / 3 N_r : 6.57 log
<i>C. albicans</i> ATCC 10231	10 ⁻⁵ : 182 / 182 10 ⁻⁶ : 28 / 30 N: 5.68 log	10 ⁻² : > 330 / > 330 10 ⁻³ : 59 / 61 10 ⁻⁴ : 11 / 5 N_c : 5.78 log	10 ⁻² : > 330 / > 330 10 ⁻³ : 55 / 68 10 ⁻⁴ : 7 / 7 N_r : 5.79 log

Table 2: Quantitative surface test according to EN 13697

Product: ECAIA +

Contact time: 60 seconds

Organic loading: 0.03% albumin

Test temperature: 18°C - 25°C

Test surface: Stainless steel

Test strain	Test suspension	Water Control N_c	Concentration: undiluted
<i>S. aureus</i> ATCC 6538	10 ⁻⁶ : 176 / 182 10 ⁻⁷ : 21 / 28 N: 6.67 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 53 / 66 10 ⁻⁵ : 3 / 5 10 ⁻⁶ : 0 / 0 N_c : 6.77 log N_{is} : > 330	10 ⁰ : 0 / 0 10 ⁻¹ : 0 / 0 10 ⁻² : 0 / 0 N_d : < 0.10 log N_{is} : 0 ME: > 6.67 log
<i>P. aeruginosa</i> ATCC 15442	10 ⁻⁶ : 248 / 240 10 ⁻⁷ : 32 / 31 N: 6.80 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 84 / 95 10 ⁻⁵ : 8 / 9 10 ⁻⁶ : 1 / 0 N_c : 6.95 log N_{is} : > 330	10 ⁰ : 0 / 0 10 ⁻¹ : 0 / 0 10 ⁻² : 0 / 0 N_d : < 0.10 log N_{is} : 0 ME: > 6.85 log

Validation to table 2:

Test strain	Test suspension	Validation N_c	Validation N_r
<i>S. aureus</i> ATCC 6538	10 ⁻⁶ : 176 / 182 10 ⁻⁷ : 21 / 28 N: 6.67 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 60 / 68 10 ⁻⁵ : 7 / 9 N_c : 6.81 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 48 / 59 10 ⁻⁵ : 4 / 6 N_r : 6.73 log
<i>P. aeruginosa</i> ATCC 15442	10 ⁻⁶ : 248 / 240 10 ⁻⁷ : 32 / 31 N: 6.80 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 80 / 98 10 ⁻⁵ : 11 / 8 N_c : 6.95 log	10 ⁻³ : > 330 / > 330 10 ⁻⁴ : 90 / 99 10 ⁻⁵ : 11 / 9 N_r : 6.98 log

Table 3: Quantitative surface test according to EN 13697

Product: ECAIA +

Contact time: 5 minutes

Organic loading: 0.03% albumin

Test temperature: 18°C - 25°C

Test surface: Stainless steel

Test strain	Test suspension	Water Control N_c	Concentration: undiluted
<i>A. brasiliensis</i> - spores ATCC 16404	10 ⁻⁵ : > 165 / > 165 10 ⁻⁶ : 26 / 26 N: 5.81 log	10 ⁻² : > 165 / > 165 10 ⁻³ : 62 / 58 10 ⁻⁴ : 5 / 5 10 ⁻⁵ : 0 / 0 N _c : 5.78 log N _{ts} : 10	10 ⁰ : 0 / 0 10 ⁻¹ : 0 / 0 10 ⁻² : 0 / 0 N _d : < 0.10 log N _{ts} : 0 ME: > 5.68 log

Validation to table 3:

Test strain	Test suspension	Validation N_c	Validation N_r
<i>A. brasiliensis</i> - spores ATCC 16404	10 ⁻⁵ : > 165 / > 165 10 ⁻⁶ : 26 / 26 N: 5.81 log	10 ⁻² : > 165 / > 165 10 ⁻³ : 50 / 58 10 ⁻⁴ : 5 / 6 N _c : 5.73 log	10 ⁻² : > 165 / > 165 10 ⁻³ : 58 / 64 10 ⁻⁴ : 5 / 6 N _r : 5.79 log

Table 4: Quantitative surface test according to EN 13697

Product: ECAIA +

Contact time: 60 minutes

Organic loading: 0.03% albumin

Test temperature: 18°C - 25°C

Test surface: Stainless steel

Test strain	Test suspension	Water Control N _c	Concentration: undiluted
<i>B. subtilis</i> - spores ATCC 6633	10 ⁻⁶ : 267 / 282 10 ⁻⁶ : 24 / 29 N: 5.84 log	10 ⁻² : > 330 / > 330 10 ⁻³ : 69 / 73 10 ⁻⁴ : 10 / 4 10 ⁻⁵ : 0 / 0 N _c : 5.85 log N _{is} : 37	10 ⁰ : 0 / 0 10 ⁻¹ : 0 / 0 10 ⁻² : 0 / 0 N _d : < 0.10 log N _{is} : 0 ME: > 5.75 log

Validation to table 4:

Test strain	Test suspension	Validation N _c	Validation N _r
<i>B. subtilis</i> - spores ATCC 6633	10 ⁻⁵ : 267 / 282 10 ⁻⁶ : 24 / 29 N: 5.84 log	10 ⁻² : > 330 / > 330 10 ⁻³ : 78 / 86 10 ⁻⁴ : 8 / 8 N _c : 5.91 log	10 ⁻² : > 330 / > 330 10 ⁻³ : 67 / 67 10 ⁻⁴ : 8 / 9 N _r : 5.83 log