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Evaluation of activity according to PN-EN 13697+A1:2019-08 (modified)

A. Laboratory:

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GLP Statement: Test procedure performed under Quality Management System according to ISO/IEC 17025, 'General Requirements for the competence of testing and calibration laboratories'; PCA accreditation N^o AB 815 PN-EN 13697+A1:2019-08 standard is in the scope of accreditation AB 815.

B. Test product data:

1. Process tested.....UV disinfection
2. Device..... **AGALINE W 2X36W T8 E 34 UV-C**
3. Test sponsor.....Luxiona Sp. z o.o.
4. Date of delivery.....05.05.2020; device provided by the test sponsor
5. Storage conditions.....ambient

C. test conditions:

1. test period.....17.05.2020 – 05.06.2020

Process description: UV emitter was mounted in the horizontal position; after 15 min from turnig it on, inoculated test carriers were placed centrally under the emitter, for the duration of the tested exposition time.

Test carriers: Petri dishes 90 mm diameter with inoculum of the test strain, 0,1 ml of inoculum from the initial count of $\sim 10^6$ cfu/ml. Inoculum was spread uniformly over the whole dish bottom.

Test carriers were positioned at: 1 m; 2 m from the emitter.

Exposition times: 2 min; 5 min; 15 min; 30 min.

After the exposition time the carriers (Petri dishes) were filled with 20 ml of 0,1% m/v Tween 80 in buffered peptone saline (Tween was added to improve the surface activity), and the bottom of the plate was scrubbed for 1 min to release the inoculum into the recovery liquid. Recovery liquid was then plated + dilutions (in the same recovery liquid) down to 10^{-2} .

Control: Petri dish with inoculum, not subjected to UV radiation, kept with the lid on over the whole duration of the test.

2. Test temperature..... $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$
3. Incubation..... $30,0^{\circ}\text{C} \pm 1,0^{\circ}\text{C}$ spores and mould, $37^{\circ}\text{C} \pm 1,0^{\circ}\text{C}$ bacteria
Plated on TSA (spores + bacteria) / MEA mould

4. Test strains:

Aspergillus brasiliensis	ATCC 16404
Bacillus subtilis	ATCC 6633 spores
Escherichia coli	ATCC 10536
Staphylococcus aureus	ATCC 6538

- D. test results..... tables 1-4

TABLE 1

test results for the disinfection process with the UV emitter **AGALINE W 2X36W T8 E 34 UV-C**
 Test temp.: 20°C ± 1°C

test sponsor: **Luxiona Sp. z o.o.**

Test strain	Test suspension N	Control	Distance 2 m							
			2 min		5 min		15 min		30 min	
Aspergillus brasiliensis ATCC 16404	10 ⁻⁵ : 11+17; 12+15	10 ⁻³ 6+9;7+7	10 ⁻¹	>55+>55; >55+>55	10 ⁻¹	>55+>55; >55+>55	10 ⁻¹	>55+>55; >55+>55	10 ⁰	31+36;29+40
			10 ⁻²	>55+>55; >55+>55	10 ⁻²	32+37;40+45	10 ⁻²	10+18;12+13	10 ⁻¹	2+4;3+5
	10 ⁻⁶ : 1+1;1+2	10 ⁻⁴ 1+1;0+1	Nd	>2,2 x 10 ⁵ Log Nd >5,34	Nd	1,5 x 10 ⁵ Log Nd =5,18	Nd	5,3 x 10 ⁴ Log Nd =4,72	Nd	1,4 x 10 ³ Log Nd = 3,15
	N: 2,8 x 10 ⁶	Nc: 2,9 x 10 ⁵ logNc = 5,46	ME	< 0,12	ME	0,28	ME	0,74	ME	2,31

Test strain	Test suspension N	Control	Distance 1 m							
			2 min		5 min		15 min		30 min	
Aspergillus brasiliensis ATCC 16404	10 ⁻⁵ : 11+17; 12+15	10 ⁻³ 6+9;7+7	10 ⁰	>55+>55; >55+>55	10 ⁰	>55+>55; >55+>55	10 ⁰	2+3;3+3	10 ⁰	1+1;1+2
			10 ⁻¹	30+37;31+39	10 ⁻¹	8+11;7+7	10 ⁻¹	0+0;0+0	10 ⁻¹	0+0;0+0
	10 ⁻⁶ : 1+1;1+2	10 ⁻⁴ 1+1;0+1	Nd	1,4 x 10 ⁴ Log Nd = 4,15	Nd	3,3 x 10 ³ Log Nd = 3,52	Nd	1,1 x 10 ² Log Nd = 2,04	Nd	5,0 x 10 ¹ Log Nd = 1,70
	N: 2,8 x 10 ⁶	Nc: 2,9 x 10 ⁵ logNc = 5,46	ME	1,31	ME	1,94	ME	3,42	ME	3,76

N – log₁₀ of the inoculum suspension count / 1 ml; 0,1 ml was inoculated onto the test surface

Control (Nc): control plate was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions

Nd – recovery from the test surface; test surface was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions

ME- reduction = log Nc – log Nd

TABLE 2

test results for the disinfection process with the UV emitter **AGALINE W 2X36W T8 E 34 UV-C**test sponsor: **Luxiona Sp. z o.o.o.**

Test temp.: 20°C ± 1°C

Test strain	Test suspension N	Control	Distance 2 m							
			2 min		5 min		15 min		30 min	
Bacillus subtilis ATCC 6633 spores	10 ⁻⁵ : 41;48	10 ⁻² 211;237	10 ⁻²	104;115	10 ⁻²	32;36	10 ⁻¹	120;134	10 ⁰	261;278
			10 ⁻³	9;12	10 ⁻³	2;4	10 ⁻²	12;16	10 ⁻¹	31;34
	10 ⁻⁶ : 4;6	10 ⁻³ 23;25	Nd	2,2 x 10 ⁵ Log Nd =5,34	Nd	6,8 x 10 ⁴ Log Nd=4,83	Nd	2,6 x 10 ⁴ Log Nd =4,42	Nd	5,5 x 10 ³ Log Nd = 3,74
	N: 4,4 x 10 ⁶	Nc: 4,5 x 10 ⁵ logNc = 5,65	ME	0,31	ME	0,82	ME	1,23	ME	1,91

Test strain	Test suspension N	Control	Distance 1 m							
			2 min		5 min		15 min		30 min	
Bacillus subtilis ATCC 6633 spores	10 ⁻⁵ : 41;48	10 ⁻² 211;237	10 ⁻¹	314;>330	10 ⁰	322;>330	10 ⁰	112;119	10 ⁰	40;47
			10 ⁻²	33;36	10 ⁻¹	29;35	10 ⁻¹	9;13	10 ⁻¹	4;6
	10 ⁻⁶ : 4;6	10 ⁻³ 23;25	Nd	6,4 x 10 ⁴ Log Nd = 4,81	Nd	6,4 x 10 ³ Log Nd = 3,81	Nd	2,3 x 10 ³ Log Nd = 3,36	Nd	8,7 x 10 ² Log Nd = 2,94
	N: 4,4 x 10 ⁶	Nc: 4,5 x 10 ⁵ logNc = 5,65	ME	0,84	ME	1,84	ME	2,29	ME	2,71

N – log₁₀ of the inoculum suspension count / 1 ml; 0,1 ml was inoculated onto the test surface
 Control (Nc): control plate was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions
 Nd – recovery from the test surface; test surface was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions
 ME- reduction = log Nc – log Nd

TABLE 3

test results for the disinfection process with the UV emitter **AGALINE W 2X36W T8 E 34 UV-C**test sponsor: **Luxiona Sp. z o.o.**

Test temp.: 20°C ± 1°C

Test strain	Test suspension N	Control	Distance 2 m							
			2 min		5 min		15 min		30 min	
Escherichia coli ATCC 10536	10 ⁻⁵ : 52;59	10 ⁻³ 71;76	10 ⁰	1;2	10 ⁰	0;0	10 ⁰	0;0	10 ⁰	0;0
			10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0
	10 ⁻⁶ : 6;8	10 ⁻⁴ 8;9	Nd	3,0 x 10 ¹ Log Nd = 1,48	Nd	< 2 Log Nd < 0,3	Nd	< 2 Log Nd < 0,3	Nd	< 2 Log Nd < 0,3
	N: 5,6 x 10 ⁶	Nc: 1,5 x 10 ⁵ logNc = 5,18	ME	3,70	ME	> 4,88	ME	> 4,88	ME	> 4,88

Test strain	Test suspension N	Control	Distance 1 m							
			2 min		5 min		15 min		30 min	
Escherichia coli ATCC 10536	10 ⁻⁵ : 52;59	10 ⁻³ 71;76	10 ⁰	0;0	10 ⁰	0;0	10 ⁰	0;0	10 ⁰	0;0
			10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0
	10 ⁻⁶ : 6;8	10 ⁻⁴ 8;9	Nd	< 2 Log Nd < 0,3	Nd	< 2 Log Nd < 0,3	Nd	< 2 Log Nd < 0,3	Nd	< 2 Log Nd < 0,3
	N: 5,6 x 10 ⁶	Nc: 1,5 x 10 ⁵ logNc = 5,18	ME	> 4,88	ME	> 4,88	ME	> 4,88	ME	> 4,88

N – log₁₀ of the inoculum suspension count / 1 ml; 0,1 ml was inoculated onto the test surface

Control (Nc): control plate was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions

Nd – recovery from the test surface; test surface was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions

ME- reduction = log Nc – log Nd

TABLE 4

test results for the disinfection process with the UV emitter **AGALINE W 2X36W T8 E 34 UV-C**test sponsor: **Luxiona Sp. z o.o.**

Test temp.: 20°C ± 1°C

Test strain	Test suspension N	Control	Distance 2 m							
			2 min		5 min		15 min		30 min	
			10 ⁰	4;6	10 ⁰	0;0	10 ⁰	0;0	10 ⁰	0;0
Staphylococcus aureus ATCC 6538	10 ⁻⁵ : 63;75	10 ⁻³ 34;39	10 ⁻¹	1;1	10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0
	10 ⁻⁶ : 5;8	10 ⁻⁴ 2;5	Nd	1,0, x 10 ⁻² Log Nd =2,00	Nd	< 2 Log Nd <0,3	Nd	< 2 Log Nd <0,3	Nd	< 2 Log Nd <0,3
	N: 6,9 x 10 ⁶	Nc: 7,3 x 10 ⁵ logNc = 5,86	ME	3,86	ME	> 5,56	ME	> 5,56	ME	> 5,56

Test strain	Test suspension N	Control	Distance 1 m							
			2 min		5 min		15 min		30 min	
			10 ⁰	0;0	10 ⁰	0;0	10 ⁰	0;0	10 ⁰	0;0
Staphylococcus aureus ATCC 6538	10 ⁻⁵ : 63;75	10 ⁻³ 34;39	10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0	10 ⁻¹	0;0
	10 ⁻⁶ : 5;8	10 ⁻⁴ 2;5	Nd	< 2 Log Nd <0,3	Nd	< 2 Log Nd <0,3	Nd	< 2 Log Nd <0,3	Nd	< 2 Log Nd <0,3
	N: 6,9 x 10 ⁶	Nc: 7,3 x 10 ⁵ logNc = 5,86	ME	> 5,56	ME	> 5,56	ME	> 5,56	ME	> 5,56

N – log₁₀ of the inoculum suspension count / 1 ml; 0,1 ml was inoculated onto the test surface

Control (Nc): control plate was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions

Nd – recovery from the test surface; test surface was covered with 20 ml of recovery liquid, scrapped and the recovery liquid was plated in duplicate, with further dilutions

ME- reduction = log Nc – log Nd

Authorized by



03.08.2020