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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

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Issue No.: 1

Test report No. S265-1/2018

DETERMINATION OF FUNGICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT **F173**

Sample ID: S265/2018

Sample name: **F173**

Client: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Producer: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Sampling point: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

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Incoming date:
10.10.2018

Delivery date:
25.2.2019

Hodonín, 25.2.2019



Ing. Jana Šlitrová, Head of Laboratory

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Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S265/2018

Rep No: 158

Sample name: **F173**

Sampled: by client

Sampling point: Christeyn France S.A., Vertou

Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018

Sample delivered: 10.10.2018

Testing date: 22.1. – 25.1.2019

Delivered amount: 800 ml

Batch No: 180613/1617-02

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Subject of testing:

Determination of fungicidal activity of the product.

Identification of the sample:

Name of the product:

F173

Batch number:

180613/1617-02

Date of manufacture:

12/01/2018

Expiry date:

12/01/2021

Manufacturer:

Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Incoming date:

10.10.2018

Storage conditions:

5 – 30 °C

Active compounds and concentrations:

CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3 diamine 5-10%

CAS 7173-51-5 Didecyldimethylammonium chloride <5 %

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-19-00 (EN 16615:2015)

Period of analysis:

22.1. – 24.1.2019

Lab temperature:

20 °C ± 2.5 °C

Temperature of media:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Product diluent:

hard water

Appearance of the product:

yellow liquid

Water control:

hard water + polysorbate 80

Test concentration:

0.1%, 0.25%, 0.4%

Contact time:

15 min

Interfering substances:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)

Test organisms:

Candida albicans ATCC 10231

Test organisms:

Aspergillus brasiliensis (niger) ATCC 16404*

Incubation conditions:

30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours

Test surface:

PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{C0} and D_{C1} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).

Wipe:

17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephthalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the product solution. The wet wipe is weighed before and after testing.

Test weight:

granite, length 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg

Tampons:

sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical

Parafilm:

Parafilm® M, 10.2 cm x 38 m, producer Brand disposable, protecting the horizontal surface and vertical surfaces before contamination during wiping,

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

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Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of *Candida albicans* under defined conditions on nonporous surface in the field 1 by at least 4 orders (10^4).

$R = D_{Ct} / N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability, the drying time: 14 – 37 min

* Strain used according to client's request

The standard:

EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015

The Number of CFU in the tested product **F173** (SOP-M-07-00 (EN ISO 4833-1)): 0 CFU/ml

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1. Testing the efficacy of chemical disinfectant F173 on *Candida albicans* ATCC 10231 on non-porous surfaces
Tab No. 1.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N _{v0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 0.4%			
V _{e1}	55	Φ _{Nv0} = 57		V _{e1}	56	Φ _B = 53		V _{e1}	38	Φ _C = 53.5	
V _{e2}	59			V _{e2}	50			V _{e2}	69		
30 < Φ _{Nv0} ≤ 160				Φ _B ≥ 0.5 Φ _{Nv0}				Φ _C ≥ 0.5 Φ _{Nv0}			
x	yes		no	x	yes		no	x	yes		no

Tab No. 1.2 Test suspension

Test suspension N	Dilution	V _{e1}	V _{e1}	Test suspension N ₀ N ₀ = N/20, lg N ₀ = 7.11 6.88 ≤ lg N ₀ ≤ 7.40			
Φ = 257 x 10 ⁶ = lg 8.41	10 ⁻⁶	288	220				
8.17 ≤ lg N ≤ 8.70	10 ⁻⁷	32	25				
				x	yes		no

Tab No. 1.2.1 Drying in time 0

Drying control (D _{c0})	Dilution	V _{e1}	V _{e1}	lg D _{c0} = lg (Φ x 5 x 10 ³) = 6.10 5.88 ≤ lg D _{c0} ≤ 7.40			
	10 ⁻³	228	284				
	10 ⁻⁴	18	25				
				x	yes		no

Tab No. 1.2.2 Drying in time t

Drying control (D _{ct})	Dilution	V _{e1}	V _{e1}	lg D _{ct} = lg (Φ x 5 x 10 ³) = 5.88 5.88 ≤ lg D _{ct} ≤ 7.40			
	10 ⁻³	151	138				
	10 ⁻⁴	23	20				
				x	yes		no

Tab No. 1.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 15	10 ⁰	3	15	yes
3 / 15	10 ⁰	4	20	yes
4 / 15	10 ⁰	3	15	yes

Tab No. 1.3.2.1 Test – the effect of F173 (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) / contact time (min) / conditions / field	Dilution after test procedure	V _c	N _a = (Φ x 5)	N _a requirement <50 cfu/25 cm ²
0.4/15/dirty/2	10 ⁰	0	<14	yes
0.4/15/dirty/3	10 ⁰	0	<14	yes
0.4/15/dirty/4	10 ⁰	0	<14	yes

Tab No. 1.3.2.2 Test – the effect of F173 (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) / contact time (min) / conditions / field	Dilution after test procedure	V _c	N _a = (Φ x 5)	N _a requirement <50 cfu/25 cm ²
0.25/15/dirty/2	10 ⁰	0	<14	yes
0.25/15/dirty/3	10 ⁰	0	<14	yes
0.25/15/dirty/4	10 ⁰	0	<14	yes

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S265/2018
 Rep No: 158
 Sample name: **F173**
 Sampled: by client
 Sampling point: Christeyn France S.A., Vertou
 Client: Christeyn France S.A., 31, Rue de la Maladrerie, Vertou

Sampling date: 8.10.2018
 Sample delivered: 10.10.2018
 Testing date: 22.1. – 25.1.2019
 Delivered amount: 800 ml
 Batch No: 180613/1617-02
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Tab No. 1.3.2.3 Test – the effect of **F173** (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm ²
0.1/15/dirty/2	10 ⁰	0	<14	yes
0.1/15/dirty/3	10 ⁰	0	<14	yes
0.1/15/dirty/4	10 ⁰	0	<14	yes

Tab No. 1.3.3 Test – the effect of **F173** (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a ($\Phi \times 5$)	lg R (lg $D_{Ct} = 5.88$)
0.4/15/dirty/1	10 ⁰	<14	<14	<1.85	≥ 4.03
0.25/15/dirty/1	10 ⁰	<14	<14	<1.85	≥ 4.03
0.1/15/dirty/1	10 ⁰	<14	<14	<1.85	≥ 4.03

Tab No. 1.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.4% solution)	19.0	17.7	1.3
F173 (Wipe with 0.25% solution)	19.3	18.3	1.0
F173 (Wipe with 0.1% solution)	19.3	17.9	1.4
Wipe with hard water + polysorbate 80	19.2	18.3	0.9

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of viable vegetative yeast cells per ml in the test mixture, A, B, C = the number of viable vegetative yeast cells per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct} / N_a$ or $lg R = lg D_{Ct} - lg N_a$ the reduction in viability

Prepared by: Ing. Barbora Stoklásková, Lab Technician
 Mgr. Karolína Světlíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

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Rep No: 158

Sample name: **F173**

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Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

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Batch No: 180613/1617-02

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2. Testing the efficacy of chemical disinfectant **F173** on *Aspergillus brasiliensis* (*niger*) ATCC 16404* on non-porous surfaces

Tab No. 2.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N _{Vo})			Neutralizer toxicity control (B)			Method validation (C), product conc. 0.4%		
V _{e1}	68	Φ _{NVo} = 56	V _{e1}	43	Φ _B = 46.5	V _{e1}	62	Φ _C = 54.5
V _{e2}	44		V _{e2}	50		V _{e2}	47	
30 ≤ Φ _{NVo} ≤ 160			Φ _B ≥ 0.5 Φ _{NVo}			Φ _C ≥ 0.5 Φ _{NVo}		
x	yes	no	x	yes	no	x	yes	no

Tab No. 2.2 Test suspension

Test suspension N	Dilution	V _{e1}	V _{e1}	Test suspension N ₀
Φ = 49 x 10 ⁷ = lg 8.69 8.17 ≤ lg N ≤ 8.70	10 ⁻⁶	> 165	> 165	N ₀ = N/20, lg N ₀ = 7.39 6.88 ≤ lg N ₀ ≤ 7.40
	10 ⁻⁷	46	52	
	x yes no			

Tab No. 2.2.1 Drying in time 0

Drying control (D _{C0})	Dilution	V _{e1}	V _{e1}	lg D _{C0} = lg (Φ x 5 x 10 ⁴) = 6.30 5.88 ≤ lg D _{C0} ≤ 7.40
	10 ⁻³	> 165	> 165	x yes no
	10 ⁻⁴	39	40	

Tab No. 2.2.2 Drying in time t

Drying control (D _{Ct})	Dilution	V _{e1}	V _{e1}	lg D _{Ct} = lg (Φ x 5 x 10 ⁴) = 6.27 5.88 ≤ lg D _{Ct} ≤ 7.40
	10 ⁻³	> 165	> 165	x yes no
	10 ⁻⁴	35	39	

Tab No. 2.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Aspergillus brasiliensis* (*niger*) ATCC 16404* on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 15	10 ⁰	20	100	yes
3 / 15	10 ⁰	10	50	yes
4 / 15	10 ⁰	3	15	yes

Tab No. 2.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Aspergillus brasiliensis* (*niger*) ATCC 16404* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) / contact time (min) / conditions / field	Dilution after test procedure	V _c	N _a = (Φ x 5)	N _a requirement <50 cfu/25 cm ²
0.4/15/dirty/2	10 ⁰	1	<14	yes
0.4/15/dirty/3	10 ⁰	0	<14	yes
0.4/15/dirty/4	10 ⁰	0	<14	yes

Tab No. 2.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Aspergillus brasiliensis* (*niger*) ATCC 16404* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) / contact time (min) / conditions / field	Dilution after test procedure	V _c	N _a = (Φ x 5)	N _a requirement <50 cfu/25 cm ²
0.25/15/dirty/2	10 ⁰	2	<14	yes
0.25/15/dirty/3	10 ⁰	3	15	yes
0.25/15/dirty/4	10 ⁰	3	15	yes

* Strain used according to client's request

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S265/2018

Rep No: 158

Sample name: F173

Sampled: by client

Sampling point: Christeyn France S.A., Vertou

Client: Christeyn France S.A., 31, Rue de la Maladrerie, Vertou

Sampling date: 8.10.2018

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Testing date: 22.1. – 25.1.2019

Delivered amount: 800 ml

Batch No: 180613/1617-02

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Tab No. 2.3.2.3 Test – the effect of F173 (Wipe with product solution) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm ²
0.1/15/dirty/2	10 ⁰	7	35	yes
0.1/15/dirty/3	10 ⁰	3	15	yes
0.1/15/dirty/4	10 ⁰	1	<14	yes

Tab No. 2.3.3 Test – the effect of F173 (Wipe with product solution) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg $N_a (\Phi \times 5)$	lg R (lg $D_{Cl} = 6.27$)
0.4/15/dirty/1	10 ⁰	<14	<14	<1.85	≥ 4.42
0.25/15/dirty/1	10 ⁰	<14	<14	<1.85	≥ 4.42
0.1/15/dirty/1	10 ⁰	35	51	2.33	3.94

Tab No. 2.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.4% solution)	19.2	17.7	1.5
F173 (Wipe with 0.25% solution)	19.4	18.2	1.2
F173 (Wipe with 0.1% solution)	19.4	18.2	1.2
Wipe with hard water + polysorbate 80	19.3	18.4	0.9

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of mould spores per ml in the test mixture, A, B, C = the number of mould spores per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Cl} / N_a$ or $lg R = lg D_{Cl} - lg N_a$ the reduction in viability

* Strain used according to client's request

Prepared by: Ing. Barbora Stoklásková, Lab Technician
Mgr. Karolína Světlíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

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3. Evaluation of fungicidal activity of the product F173

Tab No. 3.1 The efficacy of chemical disinfectant F173 on test strains – fungicidal activity on non-porous surfaces, dirty conditions, field 1

Strain	Fungicidal activity of the product (EN 16615:2015)					
	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances – conditions	lg R EN 16615:2015	lg R
<i>Candida albicans</i> ATCC 10231	20	15	0.4	dirty	≥ 4	> 4
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404*	20	15	0.4	dirty	≥ 4	> 4
<i>Candida albicans</i> ATCC 10231	20	15	0.25	dirty	≥ 4	> 4
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404*	20	15	0.25	dirty	≥ 4	> 4
<i>Candida albicans</i> ATCC 10231	20	15	0.1	dirty	≥ 4	> 4
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404*	20	15	0.1	dirty	≥ 4	< 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the test suspension, N_{V0} = the number of cfu/ml in the test suspension for validation, N_a = the number of fungi per ml in the test mixture, A, B, C = the number of fungi per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{c1} / N_a$ or $\lg R = \lg D_{c1} - \lg N_a$ the reduction in viability

* Strain used according to client's request

Prepared by: Ing. Barbora Stoklásková, Lab Technician
Mgr. Karolína Světlíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S265/2018

Rep No: 158

Sample name: F173

Sampled: by client

Sampling point: Christeyn France S.A., Vertou

Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018

Sample delivered: 10.10.2018

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Delivered amount: 800 ml

Batch No: 180613/1617-02

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Interpretation:

Results of tests are in Tabs.

According to EN 16615:2015 the tested product **F173**, batch No. 180613/1617-02, in the concentrations 0.4%, 0.25% and 0.1%, diluted in hard water (soaked wipe) and in the contact time 15 min under dirty conditions at temperature $20\text{ °C} \pm 2.5\text{ °C}$ by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable vegetative yeast cells of *Candida albicans* ATCC 10231 by at least a 4 lg reduction.

According to EN 16615:2015 the tested product **F173**, batch No. 180613/1617-02, in the concentrations 0.4% and 0.25%, diluted in hard water (soaked wipe) and in the contact time 15 min under dirty conditions at temperature $20\text{ °C} \pm 2.5\text{ °C}$ by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of mould spores of *Aspergillus brasiliensis* (*niger*) ATCC 16404* by at least a 4 lg reduction.

* Strain used according to client's request

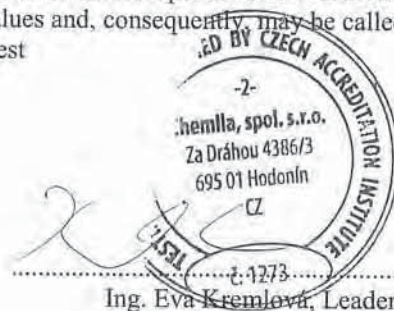
Conclusion:

The product **F173** is capable of reducing the number of viable vegetative yeast cells of the relevant organism on non-porous surfaces under defined conditions to the declared values and, consequently, may be called yeasticidal.

The product **F173** is capable of reducing the number of mould spores of the relevant organism on non-porous surfaces under defined conditions to the declared values and, consequently, may be called fungicidal*.

* The test was performed according to client's request

25.2.2019, Hodonín



Ing. Eva Kremlová, Leader of Study