

TEST REPORT

DETERMINATION OF YEASTICIDAL ACTIVITY OF THE F1031V2 PRODUCT ACCORDING TO THE EN 13624 STANDARD

Delivered to Ms CHAKCHOUK

For : **FRANKLAB**
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FRANCE



Date of request: 10/18/2018

Study number: n°268D25-2018-03

YEASTICIDAL TESTS :

According to the European standard NF EN 13624 (November 2013) – antiseptics and chemical disinfectants – quantitative suspension tests for evaluation of fungicidal activity of antiseptics and chemical disinfectants used in the medical area (phase 2, step 1).

Trials on 1 strain : *Candida albicans*.

This test report included 7 pages.

Study completion date: 11/24/2018

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

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Writer	Supervisor
Ms Emilie CANTREL, laboratory technician	Ms Stephanie MOROT-BIZOT, director
	

1. PERFORMING LABORATORY

APEX BIOSOLUTIONS
4, rue des Grandes Pièces
Zone EURESPACE
25 770 SERRE LES SAPINS
FRANCE

2. PRODUCT IDENTITY

Product	Batch #
F1031V2	611141

Expiration date: Non communicated

Manufacturer: FRANKLAB

Manufacturing date: Non communicated

Storage conditions: as recommended by the manufacturer.

Active substances: ethanol, isopropanol, tertiary amine

Appearance of the product : liquid, colorless

Diluent recommended by the manufacturer: none, ready-to-use product

Date of receipt: 10/24/2018

Date of the study: from 11/05/2018 to 11/20/2018

3. EXPERIMENTAL CONDITIONS

Final concentrations of the product: 80%

Method: dilution-neutralization

Exposure time: 2 min – 5 min - 10 min

Temperature using during the assays: 20°C

Organic soil load: clean conditions, BSA 3 g/L + 3 mL/L sheep erythrocytes

Strain: *Candida albicans* CIP 48.72 lot 265.09

Stop solution : tween 80 (30g/L) and egg yolk (5%) in distilled water.

Appearance of the product and its dilutions: clear

Diluent for fungal suspensions: trypton salt solution, sterile.

Growth conditions: MEA (Malt Extract Agar), at 30°C ± 1°.

4. RESULTS

The F1031V2 product is active against the fungal strains, because the reduction is greater than 4 log :

– *Candida albicans* R = 4,10 log

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5. CONCLUSION

According to the EN 13624 standard (November 2013), the product F1031V2:

- **Has a yeasticidal activity on the reference strain when used from the concentration 80%, for 5 min of exposure time at 20°C, in dirty conditions (BSA 3 g/L + 3 mL/L SE).**

6. SHEETS OF RESULTS

Attached below.

For all result sheets :

Control of the methodology:

- $1,5 \times 10^7 \text{ CFU/mL} \leq N \leq 5,0 \times 10^7 \text{ CFU/mL}$
- $30 \leq N_v \leq 160 \text{ CFU/mL}$
- A, B and C $\geq 0,5 \times N_v$
- The quotient of the weighted average counts is between 5 and 15

Caption:

Vc = counts per mL

$\bar{x}$ = average of Vc1 and Vc2

N = logarithm of CFU of the test suspension

Nv = number of CFU/mL in the suspension of validation

A = number of CFU/mL in the validation suspension of the experimental conditions

B = number of CFU/mL in the validation suspension of neutralizer toxicity

C = number of CFU/mL in the validation suspension of inactivation method by dilution-neutralization

Na = number of CFU/mL of the remaining germs after

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7. TRIAL - *Candida albicans*

Standard: EN 13624 Product : F1031V2 Batch N° : 611141 Study N° : 268D25-2018-03 Date of trials : 11/08/2018	Method: ☒ pour plating ☐ spread plating ☒ Number of Petri dish/mL : 2	Neutralizer : polysorbate 80 (30g/L) + egg yolk 5% Temperature: 20°C Organic soil load : 3 g/L BSA + 3 mL/L SE Incubation temperature : 30°C ± 1°C Diluent : sterile distilled water
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STRAIN	Suspension of validation Nv		Suspension of validation NvB			Validation A		Validation B		Validation C	
<i>Candida albicans</i>	30	37	1.10 ⁻³	31	33	38	43	41	39	38	51
	$\bar{x}$	33,5	$\bar{x}$	32,0		$\bar{x}$	40,5	$\bar{x}$	40,0	$\bar{x}$	44,5
	30 ≤ Nv0 ≤ 160		30 ≤ Nv0 ≤ 160			A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		C ≥ 0,5 * Nv0	
	× oui ☐ non		× oui ☐ non			× oui ☐ non		× oui ☐ non		× oui ☐ non	

STRAIN	Trial suspension			TRIAL		2 min	TRIAL		5 min	TRIAL		10 min
<i>Candida albicans</i>	1.10 ⁻⁵	208	218	Vc	85	77	Vc	18	20	Vc	0	2
	1.10 ⁻⁶	24	22	Na	810,00		Na	190,00		Na	<140	
	N	2,15.10 ⁷		Log Na	2,91		Log Na	2,28		Log Na	<2,15	
	Log N ₀	6,33		Log R = log N ₀ -log Na	3,42		Log R = log N ₀ -log Na	4,05		Log R = log N ₀ -log Na	>4,18	

Rédacteur	Superviseur
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

8. REPETITION – *Candida albicans*

Standard: EN 13624 Product : F1031V2 Batch N° : 611141 Study N° : 268D25-2018-03 Date of trials : 11/15/2018	Method: ☒ pour plating ☐ spread plating ☒ Number of Petri dish/mL : 2	Neutralizer : polysorbate 80 (30g/L) + egg yolk 5% Temperature: 20°C Organic soil load : 3 g/L BSA + 3 mL/L SE Incubation temperature : 30°C ± 1°C Diluent : sterile distilled water
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STRAIN	Suspension of validation Nv		Suspension of validation NvB			Validation A		Validation B		Validation C	
<i>Candida albicans</i>	38	43	1.10 ⁻³	40	40	44	44	40	48	39	42
	$\bar{x}$	40,5	$\bar{x}$	40,0		$\bar{x}$	44,0	$\bar{x}$	44,0	$\bar{x}$	40,5
	30 ≤ Nv0 ≤ 160		30 ≤ Nv0 ≤ 160			A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		C ≥ 0,5 * Nv0	
	× oui ☐ non		× oui ☐ non			× oui ☐ non		× oui ☐ non		× oui ☐ non	

STRAIN	Trial suspension			TRIAL			2 min	TRIAL			5 min	TRIAL			10 min
<i>Candida albicans</i>	1.10 ⁻⁵	231	227	Vc	83	84		Vc	15	19		Vc	0	0	
	1.10 ⁻⁶	30	25	Na	835,00			Na	170,00			Na	<140		
	N	2,33.10⁷		Log Na	2,92			Log Na	2,23			Log Na	<2,15		
	Log N ₀	6,37		Log R = log N ₀ -log Na	3,45			Log R = log N ₀ -log Na	4,14			Log R = log N ₀ -log Na	>4,22		

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9. TECHNICAL APPENDIX

MEDIA:

MEA (Malt Extract Agar), Dominique Dutscher, ref. 777304, batch #402241

ORGANIC SOIL LOAD :

Albumin Serum Bovine in powder, Fraction V, Dominique Dutscher, ref. P6154, batch D1304039

Sheep erythrocytes, Analytic Lab, réf. 08449, batch n°bcbj3984V

DILUENT

Trypton-Sel Solution (TS)

Per liter of distilled water:

- a) Tryptone, Dominique Dutscher, ref. 777472, batch n° 090633 -----1,00 g/L
- b) Sodium chloride, Grosseron, ref. 9020401, batch n° FR08 085 793 ----- 8,50 g/L

NEUTRALIZER

Per liter of distilled water:

- Tween 80, SIGMA ALDRICH, réf. 59924, lot n° BCBJ6978V ----- 30g/L
- Egg yolk, 5% ----- 50 mL/L

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