

TEST REPORT

DETERMINATION OF THE SPORICIDAL ACTIVITY OF THE F010760V2 PRODUCT ACCORDING TO THE EN 17126 STANDARD

Delivered to: Ms CHAKCHOUK and M CHARRAT

For: **FRANKLAB**
3 avenue des Frênes
78180 MONTIGNY LE BRETONNEUX
FRANCE



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Study references: #257D84-2023

SPORICIDAL TESTS:

According to the European standards EN 17126 (December 2018) – Chemical disinfectants and antiseptics - Quantitative suspension tests for the evaluation of sporicidal activity of disinfectants used in medical area (phase 2, step 1).

Tests using the F010760V2 product against the strain *Clostridium difficile*.

This test report includes 7 pages.



Study completion date: 10/19/2023

Stephanie MOROT - BIZOT
PhD in Microbiology
Study Director



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<u>Editor</u>	<u>Supervisor</u>
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
3, rue de la terre rouge
ESPACE INDUSTRIEL DE BEAUPRE
25220 ROCHE LEZ BEAUPRE
FRANCE

2 PRODUCT IDENTITY

Reference	Batch N°
F010760V2	8049

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: quaternary ammoniums

Appearance of the product: liquid, green

Product diluent recommended by the manufacturer for use: tap water.

Date of delivery of the product: 07/27/2023

Date of tests: 09/15/2023 to 10/03/2023

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 1.00% - 0.50%

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 15 min

Temperature using during the assays: 20°C ± 1°C

Diluent used for the assays: hard water

Diluent used for the bacterial suspensions: sterile trypton salt solution



Bacterial strain: *Clostridium difficile* NC11209 lot 10A (R027) – HPA

Media and growth conditions: TSA (Trypton Soy Agar)

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

Product stability: limpid solution with organic soil load

Stop solution: polysorbate 80 (30 g/L), with egg yolk (5%)

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4 CONCLUSIONS

According to the EN 17126 standard (December 2018), the F010760V2 product:

- Demonstrated a sporicidal activity on the reference strain *Clostridium difficile*, when used at the concentration of 1.00%, for 15 min of contact time, at 20°C, in dirty conditions

5 VALIDATIONS AND RESULTS SHEETS

Attached below.

- *Clostridium difficile*, **R = 4,09** for 15 min of contact time (1.00%)

For all result sheets:

Methodology:

- $30 \text{ UFC/ml} < N_{v0} < 160 \text{ UFC/ml}$
- $1,5 \cdot 10^7 \text{ UFC/ml} < N < 5 \cdot 10^7 \text{ UFC/ml}$
- $6,17 \leq \lg N_0 \leq 6,70$
- $A \geq 0,5 \times N_{v0}$
- $B \geq 0,5 \times N_{v0}$
- $C \geq 0,5 \times N_{v0}$



Legend:

Na = average of the number of cfu counted on Vc1 and Vc2

Log N = logarithm of the number of cfu of the microbial test suspension

Log R = logarithmic reduction obtained ($\log R = \log N_0 - \log N_a$)



VC = value counted per Petri dish

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6 RESULTS SHEET- TRIAL

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
<i>Clostridium difficile</i>	76	90	85	89	81	88	55	63
	\bar{x}	83,0	\bar{x}	87,0	\bar{x}	84,5	\bar{x}	59,0
	30 ≤ Nv0 ≤ 160 ?		A ≥ 0,5 * Nv0 ?		B ≥ 0,5 * Nv0 ?		C ≥ 0,5 * Nv0 ?	
	× yes □ no		× yes □ no		× yes □ no		× yes □ no	



TEST STRAIN	Trial suspension			TRIAL			TRIAL		
					1.00%			0.50%	
<i>Clostridium difficile</i>	1.10 ⁻⁵	249	257	Vc			Vc		
	1.10 ⁻⁶	26	30	1.10 ⁰	16	20	1.10 ⁰	101	93
	N	2,55.10 ⁷		1.10 ⁻¹	2	2	1.10 ⁻¹	13	11
	log N0	6,41		Na	180,00		Na	970,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			log Na	2,26		log Na	2,99	
	× yes □ no			Lg R = logN0-logNa			4,15	Lg R = logN0-logNa	
							3,42		

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7 RESULTS SHEET – REPETITION

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
<i>Clostridium difficile</i>	65	62	73	76	79	82	60	56
	\bar{x}	63,5	\bar{x}	74,5	\bar{x}	80,5	\bar{x}	58,0
	30 ≤ Nv0 ≤ 160 ?		A ≥ 0,5 * Nv0 ?		B ≥ 0,5 * Nv0 ?		C ≥ 0,5 * Nv0 ?	
	× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no	

TEST STRAIN	Trial suspension			TRIAL 1.00%			TRIAL 0.50%		
<i>Clostridium difficile</i>	1.10 ⁻⁵	236	225	Vc			Vc		
	1.10 ⁻⁶	25	25	1.10 ⁰	22	22	1.10 ⁰	99	82
	N	2,32.10 ⁷		1.10 ⁻¹	3	1	1.10 ⁻¹	12	10
	Log N0	6,37		Na	220,00		Na	905,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			log Na	2,34		log Na	2,96	
	× yes <input type="checkbox"/> no			Lg R = logN0-logNa	4,03		Lg R = logN0-logNa	3,41	

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8 TECHNICAL APPENDIX

Media:

BHIYT-L (Broth Heart Infusion Yeast Taurocholate L cystein), Dominique Dutscher, ref. 994057, batch 712123

ORGANIC SOIL LOAD:

Bovine serum albumin powder, Dominique Dutscher, Ref. 871001, batch D1304039

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

Diluent

Trypton-Sel Solution (TS)

Ingredients in grams per litre of distilled water:

- Trypton, Dominique Dutscher, ref. 777472, batch n ° 090633 -----1,00 g/l
- Sodium chloride, GROSSERON, ref. n° 9020401, batch n° FR08 085 793 -----8,50 g/l

pH after autoclaving at 25 °C: 7.0 ± 0.2

Stop solution

Ingredients per liter of distilled water:

- Tween 80, Sigma Aldrich, ref 59924, batch BCBJ6978V----- 30 g
- Egg yolk, ----- 50 mL

HARD WATER

Solution A: -MgCl₂ anhydrous, ref. M8266, batch n° 108K0068, SIGMA ALDRICH

- CaCl₂ Anhydrous, Ref. C1016, batch n° 059K0030, SIGMA ALDRICH

Solution B: - NaHCO₃, Ref. S6014, batch n°059K0052, SIGMA ALDRICH

pH after filtration: 7.0 ± 0.2 at 25 °C

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