

## 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**  
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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

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<u>Editor</u>	<u>Supervisor</u>
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## 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
	$\bar{x}$	<b>83,0</b>	$\bar{x}$	<b>87,0</b>	$\bar{x}$	<b>84,5</b>	$\bar{x}$	<b>59,0</b>
	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 <sup>-5</sup>	249	257	Vc			Vc		
	1.10 <sup>-6</sup>	26	30	1.10 <sup>0</sup>	16	20	1.10 <sup>0</sup>	101	93
	N	2,55.10 <sup>7</sup>		1.10 <sup>-1</sup>	2	2	1.10 <sup>-1</sup>	13	11
	log N0	<b>6,41</b>		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			<b>4,15</b>	Lg R = logN0-logNa	
							<b>3,42</b>		

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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
	$\bar{x}$	<b>63,5</b>	$\bar{x}$	<b>74,5</b>	$\bar{x}$	<b>80,5</b>	$\bar{x}$	<b>58,0</b>
	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 <sup>-5</sup>	236	225	Vc			Vc		
	1.10 <sup>-6</sup>	25	25	1.10 <sup>0</sup>	22	22	1.10 <sup>0</sup>	99	82
	N	2,32.10 <sup>7</sup>		1.10 <sup>-1</sup>	3	1	1.10 <sup>-1</sup>	12	10
	Log N0	<b>6,37</b>		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	<b>4,03</b>		Lg R = logN0-logNa	<b>3,41</b>	

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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:  $7.0 \pm 0.2$

### 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: -MgCl<sub>2</sub> anhydrous, ref. M8266, batch n° 108K0068, SIGMA ALDRICH

- CaCl<sub>2</sub> Anhydrous, Ref. C1016, batch n° 059K0030, SIGMA ALDRICH

Solution B: - NaHCO<sub>3</sub>, Ref. S6014, batch n°059K0052, SIGMA ALDRICH

pH after filtration:  $7.0 \pm 0.2$  at 25 °C

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