PERALEX 9 Hecto +

PERACETIC ACID-BASED READY-TO-USE DISINFECTANT

Franklab®
notre expertise l'Ultra-Propreté

Scientific File

PERALEX 9 Hecto +

TABLE OF CONTENTS

PERALEX 9 Hecto +

REGULATORY AND GENERAL INFORMATION

CE 0459

- Regulatory information
- ISO 13485 certificate
- ISO 9001 certificate

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REGULATORY INFORMATION

- **PERALEX 9 Hecto +** is a Class IIb medical device and is CE marked according to Directive 93/42/EC*.

- **PERALEX 9 Hecto +** is designed, manufactured and marketed by Franklab under a quality management system developed in accordance with the requirements of the international standard **ISO 13485 : 2016*.**

- **PERALEX 9 Hecto +** is designed, manufactured and marketed by Franklab under a quality management system developed in accordance with the requirements of the international standard **ISO 9001 : 2015*.**

- **PERALEX 9 Hecto +** meets our **FB Ecoline*** commitment**.**

*Full documents available on request.

EQUIVALENCE PERALEX 9 HECTO +

Formula code	FRANKLAB Designation	Packaging	FRANKLAB Commercial reference
F010474V1	Peralex 9 Hecto +	4x5L	1047420

Louisa KDYEM
Regulatory Affairs Manager

Date of creation : 18/08/2022
Date of update : 18/08/2022

PERALEX 9 Hecto +

STUDIES AND ASSESSMENTS

- Disinfectant properties
- Material compatibility
- Stability of the disinfection bath

Disinfecting properties of PERALEX 9 Hecto +

Ready-to-use high-level disinfectant

PERALEX 9 Hecto + complies with the following biocidal efficacy:

Bactericidal

Standards	Strains	Reduction of the number of viable cells	Contact time	Temperature
EN 13727 + A2: 2015 *Clean cond.*	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae*	> 5 log	1 min.	20°C
EN 14561: 2007 *Clean cond.*	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae*	> 5 log	5 min.	20°C

Yeasticidal / Fungicidal

Standards	Strains	Reduction of the number of viable cells	Contact time	Temperature
EN 13624: 2013 *Clean cond.*	*Candida albicans*	> 4 log	5 min.	20°C
EN 13624: 2013 *Clean cond.*	*Aspergillus brasiliensis (niger)*	> 4 log	5 min.	20°C
EN 14562: 2006 *Clean cond.*	*Candida albicans*	> 4 log	5 min.	20°C
EN 14562: 2006 *Clean cond.*	*Aspergillus brasiliensis (niger)*	> 4 log	5 min.	20°C

Virucidal

Standards	Strains	Reduction of the number of viable cells	Contact time	Temperature
EN 14476: 2013 *Clean cond.*	*Adenovirus VR-5*	> 4 log	5 min.	20°C
EN 14476: 2013 *Clean cond.*	*Norovirus murine*	> 4 log	5 min.	20°C
EN 14476 + A1: 2015 *Clean cond.*	*Poliovirus*	> 4 log	10 min.	20°C
EN 17111 : 2018 *Clean cond.*	*Adenovirus* *Norovirus*	> 4 log	5 min.	20°C

Tuberculocidal / Mycobactericidal

Standards	Strains	Reduction of the number of viable cells	Contact time	Temperature
EN 14348: 2005 *Clean cond.*	*Mycobacterium terrae* *Mycobacterium avium*	> 4 log	10 min.	20°C
EN 14563: 2009 *Clean cond.*	*Mycobacterium terrae* *Mycobacterium avium*	> 4 log	10 min.	20°C

Sporicidal

Standards	Strains	Reduction of the number of viable cells	Contact time	Temperature
EN 14347: 2005	*Bacillus subtilis*	> 4 log	10 min.	20°C
EN 14347: 2005	*Bacillus cereus*	> 4 log	10 min.	20°C
EN 17126: 2018 *Clean cond.*	*Bacillus subtilis*	> 4 log	10 min.	20°C
EN 17126: 2018 *Clean cond.*	*Bacillus cereus*	> 4 log	10 min.	20°C
EN 17126 : 2018 *Clean cond.*	*Clostridium difficile*	> 4 log	10 min.	20°C

REPORT OF STANDARD NF EN 13727 + A2 (2015)

Laboratory who performed the test

Hospital Hygiene Laboratory
Biology Center, 6th floor,
CHU de Clermont-Ferrand
63003 CLERMONT-FERRAND

Customer

FRANKLAB
BP 63
78185 Saint-Quentin En Yvelines

Identification of the disinfectant sample

Name of the product: F010474V1
Manufacturer: Franklab
Diluent of the product recommended by the manufacturer: None (product used pure)
Active substance(s): unspecified
Delivery date of the product: 08/02/2017
Expiration date: unspecified
Period of analysis: From 12/04/2017 to 5/5/17

- Results for Pseudomonas aeruginosa strain CIP 103.467

Test result (Repetition 1)

EN: 13 727 + A2 (Phase 2, step 1)
Name of product: F010474V1
Batch number: 5482
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons of the choice of the method: Method recommended by standard EN 13727 + A2
Neutralizer used: Polysorbate 80: 30g, Egg Lecithin: 3g, Histidine HCl: 1g, Pancreatic Casein Peptone: 1g, Sodium Chloride: 4.3g, Monopotassium Phosphate: 3.6g, Disodium Phosphate Dihydrate : 7.2g, Sodium Thiosulfate : 5g, Purified Water: qsp 1L
Test temperature: 20 °C ± 1°C
Interfering substances: **Cleaning conditions** (0.3 g/l bovine albumin)
Test strain: *Pseudomonas aeruginosa* CIP 103.467
Incubation temperature: 37°C
Date of test: 02/05/2017
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colorless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	49	$\bar{x}$=55	V_{c1}	60	$\bar{x}$ =56	V_{c1}	53	$\bar{x}$ =57	V_{c1}	33	$\bar{x}$ =39
V_{c2}	61		V_{c2}	52		V_{c2}	61		V_{c2}	45	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$? Yes [X] No [ ]			$\bar{x}$ of A is $\geq 0.5 \times \bar{x}$ of N_{vo}? Yes [X] No [ ]			$\bar{x}$ of B is $\geq 0{,}0005 \times N_{vB}$ Yes [X] No [ ]			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{vo}? Yes [X] No [ ]		
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	45	$\bar{x}$ = 49	$30 \leq \bar{x}$ of $N_{vB} / 1000 \leq 160$? Yes [X] No [ ]					
			V_{c2}	52							

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable
As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 20% here.

Test Suspension and Testing

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	$N = (224 + 205 + 27 + 21) / 2{,}2 \times 10^{-6} = 8{,}34$ log $N_0 = N/10 = 7{,}34$ log N_0 is between 7,17 and 7,70 Yes [X] No [ ]
	10^{-6}	224	205	
	10^{-7}	27	21	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	*log* N_a	*log R* (N_0=7,34)
20 %	10^0	0	0	<140	<2,15	**>5,19**
1 minute	10^{-1}	0	0			
10 %	10^0	0	0	<140	<2,15	**>5,19**
1 minute	10^{-1}	0	0			
5 %	10^0	14	19	165	2,22	**5,12**
1 minute	10^{-1}	2	0			
2,5 %	10^0	Unc	Unc	>66000	>4,82	<2,52
1 minute	10^{-1}	Unc	Unc			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: $D = [(224 + 205)/2] / [(27 + 21)/2] = 8{,}96$
8,96 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 5 log.
- ✓ No precipitate formation during the test.

Test result (Repetition 2)

EN: 13 727 + A2 (Phase 2, step 1)

Name of product: F010474V1
Batch number: 5482
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons of the choice of the method: Method recommended by standard EN 13727 + A2
Neutralizer used: Polysorbate 80: 30g, Egg Lecithin: 3g, Histidine HCl: 1g, Pancreatic Casein Peptone: 1g, Sodium Chloride: 4.3g, Monopotassium Phosphate: 3.6g, Disodium Phosphate Dihydrate : 7.2g, Sodium Thiosulfate : 5g, Purified Water: qsp 1L
Test temperature: 20 °C ± 1°C
Interfering substances: **Cleaning conditions** (0.3 g/l bovine albumin)
Test strain: *Pseudomonas aeruginosa* CIP 103.467
Incubation temperature: 37°C
Date of test: 02/05/2017
Diluent used for product test solutions: Sterile distilled water
Aspect of the of product dilutions: Liquid, colorless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	55	$\bar{x}$ = 62	V_{c1}	53	$\bar{x}$ = 52	V_{c1}	57	$\bar{x}$ = 63	V_{c1}	60	$\bar{x}$ = 58
V_{c2}	68		V_{c2}	51		V_{c2}	68		V_{c2}	56	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160?			$\bar{x}$ of *A* is ≥ 0.5 x $\bar{x}$ of N_{vo} ?			$\bar{x}$ of *B* is ≥ 0,0005 x N_{vB}			$\bar{x}$ of *C* is ≥ 0.5 x $\bar{x}$ of N_{vo}?		
Yes [X]	No [ ]		Yes [X]	No [ ]		Yes [X]	No [ ]		Yes [X]	No [ ]	
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	60	$\bar{x}$ = 65	30 ≤ $\bar{x}$ of N_{vB} / 1000 ≤ 160?					
			V_{c2}	69		Yes [X]	No [ ]				

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable
As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 20% here.

Test Suspension and Testing

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	N = (332 + 349 + 33 + 37) / 2,2x10^{-6} = 8,53 log N_0 = N/10 = 7,53 log N^0 is between 7,17 and 7,70
	10^{-6}	332	349	Yes [X] No [ ]
	10^{-7}	33	37	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	N_a= $\bar{x}$ x10	*log* N_a	*log R* (N_0=7,53)
20 %	10^0	0	0	<140	<2,15	**>5,38**
1 minute	10^{-1}	0	0			
10 %	10^0	0	0	<140	<2,15	**>5,38**
1 minute	10^{-1}	0	0			
5 %	10^0	1	1	<140	2,15	**5,38**
1 minute	10^{-1}	0	0			
2,5 %	10^0	Unc	Unc	>66000	>4,82	<2,71
1 minute	10^{-1}	Unc	Unc			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(332 + 349)/2] / [(33 + 37)/2] = 9,74
9,74 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 5 log.
- ✓ No precipitate formation during the test.

- Results for Staphylococcus aureus strain CIP 4.83

Test result (Repetition 1)

EN: 13 727 + A2 (Phase 2, step 1)

Name of product: F010474V1
Batch number: 5482
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons for the choice of the method: Method recommended by standard EN 13727 + A2
Neutralizer used: Polysorbate 80: 30g, Egg Lecithin: 3g, Histidine HCl: 1g, Pancreatic Casein Peptone: 1g, Sodium Chloride: 4.3g, Monopotassium Phosphate: 3.6g, Disodium Phosphate Dihydrate : 7.2g, Sodium Thiosulfate : 5g, Purified Water: qsp 1L
Test temperature: 20 °C ± 1°C
Interfering substances: **Cleaning conditions** (0.3 g/l bovine albumin)
Test strain: *Staphylococcus aureus CIP 4.83*
Incubation temperature: 37°C
Date of test: 12/04/2017
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colorless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	41	$\bar{x}$ = 39	V_{c1}	30	$\bar{x}$ = 33	V_{c1}	49	$\bar{x}$ = 45	V_{c1}	37	$\bar{x}$ = 37
V_{c2}	36		V_{c2}	35		V_{c2}	41		V_{c2}	37	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160?			$\bar{x}$ of A is ≥ 0.5 x $\bar{x}$ of N_{vo} ?			$\bar{x}$ of B is ≥ 0,0005 x N_{vB}			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of N_{vo}?		
Yes [X]	No [ ]		Yes [X]	No [ ]		Yes [X]	No [ ]		Yes [X]	No [ ]	
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	41	$\bar{x}$ = 46	30 ≤ $\bar{x}$ of N_{vB} / 1000 ≤ 160?					
			V_{c2}	51		Yes [X]	No [ ]				

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 40% here.

Test Suspension and Testing

	N	V_{c1}	V_{c2}	
Test suspension (N and N_0)	10^{-6}	179	170	N = (179 + 170 + 15 + 17) / $2{,}2 \times 10^{-6}$ = 8,24 log N_0 = N/10 = 7,24 log N^0 is between 7,17 and 7,70 Yes [X] No [ ]
	10^{-7}	15	17	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	*log* N_a	*log R* (N_0=7,24)
40 % **1 minute**	10^0	0	0	<140	<2,15	**>5,09**
	10^{-1}	0	0			
20 % **1 minute**	10^0	0	0	<140	<2,15	**>5,09**
	10^{-1}	1	0			
10 % 1 minute	10^0	Unc	Unc	>66000	>4,82	<2,27
	10^{-1}	>660	>660			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(179 + 170)/2] / [(15 + 17)/2] = 10,9
10,9 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 5 log.
- ✓ No precipitate formation during the test.

Test result (Repetition 2)

EN: 13 727 + A2 (Phase 2, step 1)

Name of product: F010474V1
Batch number: 5482
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons for the choice of the method: Method recommended by standard EN 13727 + A2
Neutralizer used: Polysorbate 80: 30g, Egg Lecithin: 3g, Histidine HCl: 1g, Pancreatic Casein Peptone: 1g, Sodium Chloride: 4,3g, Monopotassium Phosphate: 3,6g, Disodium Phosphate Dihydrate : 7,2g, Sodium Thiosulfate : 5g, Purified Water: qsp 1L
Test temperature: 20 °C ± 1°C
Interfering substances: **Cleaning conditions** (0,3 g/l bovine albumin)
Test strain: *Staphylococcus aureus CIP 4.83*
Incubation temperature: 37°C
Date of test: 12/04/2017
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colorless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	66	$\bar{x}$ = 66	V_{c1}	62	$\bar{x}$ = 68	V_{c1}	58	$\bar{x}$ = 60	V_{c1}	63	$\bar{x}$ = 66
V_{c2}	65		V_{c2}	74		V_{c2}	62		V_{c2}	68	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? Yes [X] No [ ]			$\bar{x}$ of A is ≥ 0.5 x $\bar{x}$ of N_{vo}? Yes [X] No [ ]			$\bar{x}$ of B is ≥ 0,0005 x N_{vB} Yes [X] No [ ]			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of N_{vo}? Yes [X] No [ ]		
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	72	$\bar{x}$ = 79	30 ≤ $\bar{x}$ of N_{vB} / 1000 ≤ 160? Yes [X] No [ ]					
			V_{c2}	86							

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable
As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 40% here.

Test Suspension and Testing

	N	V_{c1}	V_{c2}	
Test suspension (N and N_0)	10^{-6}	298	318	N = (298 + 318 + 39 + 57) / $2{,}2 \times 10^{-6}$ = 8,51 log N_0 = N/10 = 7,51 log N^0 is between 7,17 and 7,70 Yes [X] No [ ]
	10^{-7}	39	57	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	N_a= $\bar{x}$ x10	*log* N_a	*log R* (N_0=7,51)
40 %	10^0	0	0	<140	<2,15	**>5,36**
1 minute	10^{-1}	0	0			
20 %	10^0	1	0	<140	<2,15	**>5,36**
1 minute	10^{-1}	0	0			
10 %	10^0	Unc	Unc	>66000	>4,82	<2,69
1 minute	10^{-1}	Unc	Unc			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(298 + 318)/2] / [(39 + 57)/2] = 6,42
6,42 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 5 log.
- ✓ No precipitate formation during the test.

- Results for Enterococcus hirae strain CIP 58.55

Test result (Repetition 1)

EN: 13 727 + A2 (Phase 2, step 1)

Name of product: F010474V1
Batch number: 5482
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons for the choice of the method: Method recommended by standard EN 13727 + A2
Neutralizer used: Polysorbate 80: 30g, Egg Lecithin: 3g, Histidine HCl: 1g, Pancreatic Casein Peptone: 1g, Sodium Chloride: 4,3g, Monopotassium Phosphate: 3,6g, Disodium Phosphate Dihydrate : 7,2g, Sodium Thiosulfate : 5g, Purified Water: qsp 1L
Test temperature: 20 °C ± 1°C
Interfering substances: **Cleaning conditions** (0,3 g/l bovine albumin)
Test strain: *Enterococcus hirae* CIP 58.55
Incubation temperature: 37°C
Date of test: 03/05/17
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colorless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	118	$\bar{x}$ = 110	V_{c1}	102	$\bar{x}$ = 105	V_{c1}	69	$\bar{x}$ = 69	V_{c1}	103	$\bar{x}$ = 97
V_{c2}	101		V_{c2}	108		V_{c2}	69		V_{c2}	91	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160?			$\bar{x}$ of A is ≥ 0.5 x $\bar{x}$ of N_{vo} ?			$\bar{x}$ of B is ≥ 0,0005 x N_{vB}			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of N_{vo}?		
Yes [X]	No [ ]		Yes [X]	No [ ]		Yes [X]	No [ ]		Yes [X]	No [ ]	
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	85	$\bar{x}$ = 87	30 ≤ $\bar{x}$ of N_{vB} / 1000 ≤ 160 ?					
			V_{c2}	88		Yes [X]	No [ ]				

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 40% here.

Test Suspension and Testing

	N	V_{c1}	V_{c2}	
Test suspension (N and N_0)	10^{-6}	459	429	N = (459 + 429 + 56 + 65) / $2{,}2 \times 10^{-6}$ = 8,66 log N_0 = N/10 = 7,66 log N_0 is between 7,17 and 7,70? Yes [X] No [ ]
	10^{-7}	56	65	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	*log* N_a	*log R* (N_0=7,66)
40 % 1 minute	10^0	0	0	<140	<2,15	**>5,51**
	10^{-1}	0	0			
20 % 1 minute	10^0	0	0	<140	<2,15	**>5,51**
	10^{-1}	0	0			
10 % 1 minute	10^0	Unc	Unc	>66000	>4,82	<2,84
	10^{-1}	Unc	Unc			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(459 + 429)/2] / [(56 + 65)/2] = 7,34
7,34 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 5 log.
- ✓ No precipitate formation during the test.

Test result (Repetition 2)

EN: 13 727 + A2 (Phase 2, step 1)

Name of product: F010474V1
Batch number: 5482
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons for the choice of the method: Method recommended by standard EN 13727 + A2
Neutralizer used: Polysorbate 80: 30g, Egg Lecithin: 3g, Histidine HCl: 1g, Pancreatic Casein Peptone: 1g, Sodium Chloride: 4.3g, Monopotassium Phosphate: 3.6g, Disodium Phosphate Dihydrate : 7.2g, Sodium Thiosulfate : 5g, Purified Water: qsp 1L
Test temperature: 20 °C ± 1°C
Interfering substances: **Cleaning conditions** (0,3 g/l bovine albumin)
Test strain: *Enterococcus hirae* CIP 58.55
Incubation temperature: 37°C
Date of test: 03/05/2017
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colourless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	97	$\bar{x}$ =102	V_{c1}	90	$\bar{x}$ = 96	V_{c1}	95	$\bar{x}$ = 84	V_{c1}	91	$\bar{x}$ = 83
V_{c2}	107		V_{c2}	101		V_{c2}	72		V_{c2}	75	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? Yes [X] No [ ]			$\bar{x}$ of *A* is ≥ 0.5 x $\bar{x}$ of N_{vo} ? Yes [X] No [ ]			$\bar{x}$ of *B* is ≥ 0,0005 x N_{vB} Yes [X] No [ ]			$\bar{x}$ of *C* is ≥ 0.5 x $\bar{x}$ of N_{vo}? Yes [X] No [ ]		
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	92	$\bar{x}$ =105	30 ≤ $\bar{x}$ of N_{vB} / 1000 ≤ 160 ? Yes [X] No [ ]					
			V_{c2}	117							

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable
As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 40% here.

Test Suspension and Testing

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	N = (331 + 357 + 43 + 49) / $2{,}2\times10^{-6}$ = 8,55 log N_0 = N/10 = 7,55 log N_0 is between 7,17 and 7,70 Yes [X] No [ ]
	10^{-6}	331	357	
	10^{-7}	43	49	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	N_a= $\bar{x}$ x10	*log* N_a	*log R* (N_0=7,55)
40 %	10^0	0	0	<140	<2,15	**>5,40**
1 minute	10^{-1}	0	0			
20 %	10^0	0	0	<140	<2,15	**>5,40**
1 minute	10^{-1}	0	0			
10 %	10^0	Unc	Unc	>66000	>4,82	<2,73
1 minute	10^{-1}	Unc	Unc			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(331 + 357)/2] / [(43 + 49)/2] = 7,48
7,48 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 5 log.
- ✓ No precipitate formation during the test.

Conclusion

Tests were performed on strains referenced as *Staphylococcus aureus* CIP 4.83, *Enterococcus hirae* CIP 58.55, *Pseudomonas aeruginosa* CIP 103.467. The tests were carried out twice. The reduction with the test strain *Staphylococcus aureus* in I minute at 20% is $1.68.10^5$ or 5,23 log.

In accordance with standard **EN 13727 + A2 (2015)**, batch **5482** of **F010474V1,** when concentrated at **20%** (V/V) in **sterile distilled water** (Product used pure), shows **bactericidal** activity in **1 minute** at **20°C**, under **clean conditions** (0.3 g/l of bovine albumin), with respect to the referenced strain Staphylococcus aureus, for disinfection of medical devices.

Clermont-Ferrand, le 16/05/2017

HYGIENE HOSPITALIERE
Centre de Biologie - 6ème Etage
CHU
63003 Clermont-Ferrand Cedex 1
Tél. : 04 73 754 870 - Fax : 04 73 754 871

TEST REPORT

DETERMINATION OF THE BACTERICIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE ON 14561 STANDARD

Delivered to: Ms CHAKCHOUK

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

Date of request: 07/17/2014

Study references: n°295D11-2014-06

BACTERICIDAL TESTS:

According to the European standard EN 14561 (March 2007) – Chemical disinfectants and antiseptics. Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants used in human medicine.

Tests using the F010474V1 product against 3 reference strains: *Staphylococcus aureus, Pseudomonas aeruginosa* and *Enterococcus hirae*.

This test report included 17 pages.

Study completion date: 12/21/2014

Stephanie MOROT - BIZOT
PhD in Microbiology
Study Director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

Echantillon	N° BATCH
F010474V1	4494

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: peracetic acid

Appearance of the product: clear.

Product diluent recommended by the manufacturer for use: none, ready-to-use product.

Date of delivery of the product: 12/02/2014

Date of tests: 12/18/2014 to 12/19/2014

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 100.0% - 1.0%

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 5 min – 10 min – 15 min – 60 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 strains: *Staphylococcus aureus* subsp. *aureus* CIP 4.83 batch 15713-1d (ATCC 6538), *Pseudomonas aeruginosa* DSM 939 batch 0413 (ATCC 15442) and *Enterococcus hirae* DSM 3320 batch 0511 (ATCC 10541) - Institut Pasteur.

Media and growth conditions: TSA (Trypton Soy Agar), at 37°C ± 1°C.

Organic soil load: clean conditions, BSA 0,3 g/L

Product stability: limpid solution with organic soil load

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

4 RESULTS

See sheets of results.

- S. *aureus*, R > 5,03
- *P. aeruginosa*, R > 5,05
- *E. hirae*, R > 5,03

5 CONCLUSION

According to the EN 14561 standard (March 2007), the F010474V1, batch n°4494 product :

- **Demonstrated a bactericidal activity on the reference strains when used at the concentration of 100%, for 5 min of contact time, at 20 °C, in clean conditions (0,3 g/L bovine albumin)**

6 SHEETS OF RESULTS

See above.

For all result sheets :

Methodology:
- 30 UFC/mL < Nv0 < 160 UFC/mL
- 1,5.10^9 UFC/mL < N < 5.10^9 UFC/mL
- 5,17 ≤ log N0 ≤ 5,70
- A ≥ 0,5 x Nv0
- B ≥ 0,5 x Nv0
- C ≥ 0,5 x Nv0
- 1,4 x 10^6 UFC/mL < Nw < log N-1,3

Legend :

$\bar{x}$ = 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 N0 – log Na)
VC = value counted per Petri dish
Nv = number of CFU/mL in the suspension of validation
A = number of CFU/mL in the control of experimental conditions
B = number of CFU/mL in the control of neutralizer toxicity
C = number of CFU/mL in the control of neutralization method
Na = number of survivor per mL after time exposure with the product

SHEET OF RESULTS 1 -
***Enterococcus hirae* (TRIAL)**

STANDARD : EN 14561, phase 2 step 2
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ Pour plating
☐ Spread plating
☒ Number of plates /ml : 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%).

Trial temperature : 20°C.

Organic soil load : BSA 0,3 g/L

STRAIN : *Enterococcus hirae* (DSM 3320, lot 0511)

Incubation temperature : 37°C ± 1°C

STUDY N° 295D11-2014-06 DATE OF TRIALS: 12/18/2014

Study director : Ms Stephanie MOROT-BIZOT Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validations and controls

	Suspension of validation Nv0		Experimental conditions control A		Control of neutralizer B		Control of method C	
Vc1	78	$\bar{x}$	80	$\bar{x}$	78	$\bar{x}$	75	$\bar{x}$
Vc2	91	84,5	81	80,5	75	76,5	70	72,5
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A est ≥0,5 × $\bar{x}$ ofNv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ ofNv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ ofNv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Test suspension and trial

Test suspension (N)			log N
10^{-7}	299	269	9,45
10^{-8}	30	28	
9,17 ≤ N ≤ 9,70? x yes □ no			

Water control(Nw)			log Nw
10^{-4}	141	153	7,17
7,15 ≤ Nw ≤ lg N-1,3? x yes □ no			

	TRIAL									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		1% 15 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	>330	>330
10^{-2}	0	0	0	0	0	0	0	0	49	49
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		4,69	
log R = log Nw - log Na	**>5,02**		**>5,02**		**>5,02**		**>5,02**		2,48	

SHEET OF RESULTS 2 -
***Staphylococcus aureus* (TRIAL)**

STANDARD: EN 14561, phase 2 step2
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ pour plating
☐ Spread plating
☒ Number of plates /ml : 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%).

Trial temperature: 20°C.

Organic soil load: BSA 0,3 g/L

STRAIN: *Staphylococcus aureus* (DSM 799, lot 0413)

Incubation temperature: 37°C ± 1°C

STUDY N° 295D11-2014-06 DATE OF TRIALS: 12/18/2014

Study director : Ms MOROT-BIZOT Stephanie Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validations and controls

	Suspension of validation Nv0		Experimental conditions control A		Control of neutralizer B		Control of method C	
Vc1	39	$\bar{x}$	90	$\bar{x}$	82	$\bar{x}$	90	$\bar{x}$
Vc2	44	41,5	87	88,5	88	85	89	89,5
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A est ≥0,5 × $\bar{x}$ ofNv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ ofNv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ ofNv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Test suspension and trial

Test suspension (N)			log N
10^{-7}	203	219	9,33
10^{-8}	21	28	
9,17 ≤ N ≤ 9,70? x yes □ no			

Water control (Nw)			log Nw
10^{-4}	153	151	7,18
7,15 ≤ Nw ≤ lg N-1,3? x yes □ no			

	TRIAL									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		1% 15 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	>330	>330
10^{-2}	0	0	0	0	0	0	0	0	40	43
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		<2,15	
log R = log Nw - log Na	**>5,03**		**>5,03**		**>5,03**		**>5,03**		**>5,03**	

SHEET OF RESULTS 3 -
***Pseudomonas aeruginosa* (TRIAL)**

STANDARD: EN 14561, phase 2 step2
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ Spour plating
☐ Spread plating
☒ Number of plates /ml : 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%).

Trial temperature: 20°C.

Organic soil load: BSA 0,3 g/L

STRAIN: *Pseudomonas aeruginosa* (DSM 939, lot 0413)

Incubation temperature : 37°C ± 1°C

STUDY N° 295D11-2014-06 DATE OF TRIALS: 12/18/2014

Study director : Ms MOROT-BIZOT Stephanie Signature :

Diluant used for the produtc's dilutions: distilled water

Appearance of the product's dilutions: clear

Validations and controls

	Suspension of validation Nv0		Experimental conditions control A		Control of neutralizer B		Control of method C	
Vc1	38	$\bar{x}$	58	$\bar{x}$	90	$\bar{x}$	60	$\bar{x}$
Vc2	35	36,5	73	65,5	48	69	59	59,5
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A est ≥0,5 × $\bar{x}$ ofNv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ ofNv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ ofNv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Test suspension and trial

Test suspension (N)			log N
10^{-7}	229	235	9,37
10^{-8}	23	28	
9,17 ≤ N ≤ 9,70? x yes □ no			

Water control (Nw)			log Nw
10^{-4}	160	158	7,20
7,15 ≤ Nw ≤ lg N-1,3? x yes □ no			

	TRIAL									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		1% 15 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	>330	>330
10^{-2}	0	0	0	0	0	0	0	0	38	33
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		4,55	
log R = log Nw - log Na	**>5,05**		**>5,05**		**>5,05**		**>5,05**		2,65	

SHEET OF RESULTS 4 -
***Enterococcus hirae* (REPETITION)**

STANDARD: EN 14561, phase 2 step2
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ Spour plating
☐ Spread plating
☒ Number of plates /ml : 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%).

Trial temperature: 20°C.

Organic soil load: BSA 0,3 g/L

STRAIN: *Enterococcus hirae* (DSM 3320, lot 0511)

Incubation temperature : 37°C ± 1°C

STUDY N° 295D11-2014-06 DATE OF TRIALS : 12/18/2014

Study director : Ms MOROT-BIZOT Stephanie Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validations and controls

	Suspension of validation Nv0		**Experimental conditions control A**		**Control of neutralizer B**		**Control of method C**	
Vc1	63	$\bar{x}$	63	$\bar{x}$	54	$\bar{x}$	49	$\bar{x}$
Vc2	59	61	61	62	55	54,5	49	49
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A est ≥0,5 × $\bar{x}$ ofNv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ ofNv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ ofNv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Test suspension and trial

Test suspension (N)			log N
10^{-7}	299	269	9,45
10^{-8}	30	28	
9,17 ≤ N ≤ 9,70? x yes □ no			

Water control(Nw)			log Nw
10^{-4}	149	159	7,19
7,15 ≤ Nw ≤ lg N-1,3? x yes □ no			

	TRIAL									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		1% 15 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	>330	>330
10^{-2}	0	0	0	0	0	0	0	0	39	28
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		4,53	
log R = log Nw - log Na	>5,04		>5,04		>5,04		>5,04		2,66	

SHEET OF RESULTS 5 -
***Staphylococcus aureus* (REPETITON)**

STANDARD: EN 14561, phase 2 step2
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ Spour plating
☐ Spread plating
☒ Number of plates /ml : 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%).

Trial temperature: 20°C.

Organic soil load: BSA 0,3 g/L

STRAIN: *Staphylococcus aureus* (DSM 799, lot 0413)

Incubation temperature: 37°C ± 1°C

STUDY N° 295D11-2014-06 DATE OF TRIALS: 12/18/2014

Study director : Ms MOROT-BIZOT Stephanie Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validations and controls

	Suspension of validation Nv0		**Experimental conditions control A**		**Control of neutralizer B**		**Control of method C**	
Vc1	39	**$\bar{x}$**	65	**$\bar{x}$**	56	**$\bar{x}$**	48	**$\bar{x}$**
Vc2	44	41,5	62	63,5	59	57,5	48	48
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A est ≥0,5 × $\bar{x}$ ofNv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ ofNv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ ofNv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Test suspension and trial

Test suspension (N)			log N
10^{-7}	203	219	9,33
10^{-8}	21	28	
9,17 ≤ N ≤ 9,70? x yes □ no			

Water control (Nw)			log Nw
10^{-4}	155	138	7,17
7,15 ≤ Nw ≤ lg N-1,3? x yes □ no			

	TRIAL									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		1% 15 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	>330	>330
10^{-2}	0	0	0	0	0	0	0	0	34	31
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		4,51	
log R = log Nw - log Na	>5,02		>5,02		>5,02		>5,02		2,65	

SHEET OF RESULTS 6 -
***Pseudomonas aeruginosa* (REPETITION)**

STANDARD: EN 14561, phase 2 step2
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ Spour plating
☐ Spread plating
☒ Number of plates /ml : 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%).

Trial temperature: 20°C.

Organic soil load: BSA 0,3 g/L

STRAIN: *Pseudomonas aeruginosa* (DSM 939, lot 0413)

Incubation temperature : 37°C ± 1°C

STUDY N° 295D11-2014-06 DATE OF TRIALS: 12/18/2014

Study director : Ms MOROT-BIZOT Stephanie Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validations and controls

	Suspension of validation Nv0		Experimental conditions control A		Control of neutralizer B		Control of method C	
Vc1	38	$\bar{x}$	48	$\bar{x}$	43	$\bar{x}$	41	$\bar{x}$
Vc2	35	36,5	56	52	49	46	42	41,5
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A est ≥0,5 × $\bar{x}$ ofNv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ ofNv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ ofNv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Test suspension and trial

Test suspension (N)			log N
10^{-7}	229	235	9,37
10^{-8}	23	28	
9,17 ≤ N ≤ 9,70? x yes □ no			

Water control Nw)			log Nw
10^{-4}	160	158	7,20
7,15 ≤ Nw ≤ lg N-1,3? x yes □ no			

	TRIAL									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		1% 15 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	>330	>330
10^{-2}	0	0	0	0	0	0	0	0	38	32
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		4,54	
log R = log Nw - log Na	>5,05		>5,05		>5,05		>5,05		2,66	

7 TECHNICAL APPENDIX

Media:

TSA (Trypton Soy Agar), Dominique Dutscher, ref. 777410, batch 409161

ORGANIC SOIL LOAD:

Bovine serum albumin powder, Dominique Dutscher, Ref. P6154, batch M10637P6154

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

Diluent

Trypton-Sel Solution (TS)

Ingredients in grams per litre of distilled water:

a) Trypton, Dominique Dutscher, ref. 1612, batch n ° 090633 ----------1,00 g/l

b) Sodium chloride, Grosseron, ref 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, lot BCBJ6978V ---------- 30 g/L
- Egg yolk ---------- 50 g/L

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

GLASS CARRIERS – frosted glass blades, 15 x 60 mm, 1 mm thick – Thermo scientific/ Menzel-Gläser – ref. 100 OTM, batch n°01 1794389.

REPORT OF STANDARD NF EN 13624 (2013)

Laboratory who performed the test

Hospital Hygiene Laboratory
Biology Center, 6th floor,
CHU de Clermont-Ferrand
63003 CLERMONT-FERRAND

Customer

FRANKLAB
BP 63
78185 Saint-Quentin En Yvelines

Identification of the disinfectant sample

Name of the product: F010474V1
Manufacturer: Franklab
Diluent of the product recommended by the manufacturer: None (product used pure)
Active substance(s): unspecified
Delivery date of the product: 19/11/14
Expiration date: Unspecified
Period of analysis: From 12/1/15 to 15/1/15

Test result

EN: 13 624 (Phase 2, step 1)
Name of product: F010474V1
Batch number: 4494
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons of the choice of the method: Method recommended by standard EN 13624
Neutralizer used: Pancreatic digest of casein 17g, Soya enzymatic digestion 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2,5g, Glucose 2,5g, Polysorbate 80 30 ml, Sodium pyruvate 30g, distilled Water: qsp 1L
Agar used : Malta extract agar
Test temperature: 20 °C
Interfering substances: **Cleaning conditions** (BSA 0,3 g/l)
Test strain: *Candida albicans* IP 48.72
Incubation temperature: 30°C
Date of test: 12/1/15
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colourless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	39	$\bar{x}$=41	V_{c1}	43	$\bar{x}$=41	V_{c1}	30	$\bar{x}$=33	V_{c1}	27	$\bar{x}$ = 26
V_{c2}	43		V_{c2}	39		V_{c2}	36		V_{c2}	25	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$? Yes [X] No [ ]			$\bar{x}$ of A is $\geq 0.5 \times \bar{x}$ of N_{vo}? Yes [X] No [ ]			$\bar{x}$ of B is $\geq 0{,}0005 \times N_{vB}$ Yes [X] No [ ]			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{vo}? Yes [X] No [ ]		
Suspension of validation (N_{vB}), 10^{-3}	V_{c1}	29	$\bar{x}$ = 32	$30 \leq \bar{x}$ of $N_{vB} / 1000 \leq 160$? Yes [X] No [ ]							
	V_{c2}	34									

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; unc: Uncountable
As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 80% here.

Test Suspension and Testing

	N	V_{c1}	V_{c2}	
Test suspension (N and N_0)	10^{-5}	158	159	$N = (158 + 159 + 23 + 26) / 2{,}2 \times 10^{-5} = 7{,}22$ log $N_0 = N/10 = 6{,}22$ log N_0 is between 6,17 and 6,70 Yes [X] No [ ]
	10^{-6}	23	26	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	*log* N_a	*log R* (N_0=6,54)
80 %	10^0	4*	0*	<140	<2,15	**>4,07**
5 minutes	10^{-1}	0	0			
40 %	10^0	0*	0*	<140	<2,15	**>4,07**
5 minutes	10^{-1}	0	0			
8 %	10^0	0*	0*	<140	<2,15	**>4,07**
5 minutes	10^{-1}	0	0			
0,8 %	10^0	Unc	Unc	>33000	>4,52	<1,70
5 minutes	10^{-1}	Unc*	Unc*			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(158 + 159)/2] / [(23 + 26)/2] = 6,5
6,5 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 4 log.
- ✓ No precipitate formation during the test.

Conclusion

Tests were performed on strains referenced as *Candida albicans* IP 48.72. The tests were carried out once. The reduction with the test strain *C.albicans* in 5 minutes at 8% is $1,2.10^4$ or 4,07 log.

In accordance with standard **EN 13624 (2013)**, batch **4494** of **F010474V1,** when concentrated at **8%** (V/V) in **sterile distilled water** (Product used pure), shows **yeasticidal** activity in **5 minutes** at **20°C**, under **clean conditions (BSA 0.3 g/l)**, with respect to the referenced strain *Candida albicans*, for disinfection of medical devices.

Clermont-Ferrand, le 28/01/2015

HYGIENE HOSPITALIERE
Centre de Biologie - 6ème Etage
CHU
63003 Clermont-Ferrand Cedex 1
Tél. : 04 73 754 870 - Fax : 04 73 754 871

REPORT OF STANDARD NF EN 13624 (2013)

Laboratory who performed the test

Hospital Hygiene Laboratory
Biology Center, 6th floor,
CHU de Clermont-Ferrand
63003 CLERMONT-FERRAND

Customer

FRANKLAB
BP 63
78185 Saint-Quentin En Yvelines

Identification of the disinfectant sample

Name of the product: F010474V1
Manufacturer: Franklab
Diluent of the product recommended by the manufacturer: None (product used pure)
Active substance(s): unspecified
Delivery date of the product: 19/11/14
Expiration date: unspecified
Period of analysis: From 9/12/14 to 12/12/14

Test result

EN: 13 624 (Phase 2, step 1)
Name of product: F010474V1
Batch number: 4494
Manufacturer: Franklab
Aspect of the product: Liquid, colorless, acetic odor
Storage conditions (temperature, etc.): Darkness, room temperature

Dilution-neutralization method:

Reasons of the choice of the method: Method recommended by standard EN 13624
Neutralizer used: Pancreatic digest of casein 17g, Soya enzymatic digestion 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30 ml, Sodium pyruvate 30g, Water: qsp 1L
Agar used : Malta extract agar
Test temperature: 20 °C
Interfering substances: **Cleaning conditions** (BSA 0.3 g/l)
Test strain: *Aspergillus brasiliensis* IP 481.83
Incubation temperature: 30°C
Date of test: 9/12/14
Diluent used for product test solutions: Sterile distilled water
Aspect of the product dilutions: Liquid, colorless
Aspect of the product during the test: Absence of precipitate

Validation and Witnesses

Suspension of validation (N_{vo})			Control of experimental conditions (A)			Neutralizer toxicity indicator (B)			Validation of the method (C)		
V_{c1}	97	$\bar{x}$=85	V_{c1}	89	$\bar{x}$=88	V_{c1}	59	$\bar{x}$	V_{c1}	89	$\bar{x}$=91
V_{c2}	72		V_{c2}	87		V_{c2}	79	=69	V_{c2}	92	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? Yes [X] No [ ]			$\bar{x}$ of A is ≥ 0.5 x $\bar{x}$ of N_{vo}? Yes [X] No [ ]			$\bar{x}$ of B is ≥ 0,0005 x N_{vB} Yes [X] No [ ]			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of N_{vo}? Yes [X] No [ ]		
Suspension of validation (N_{vB}), 10^{-3}			V_{c1}	92	$\bar{x}$= 88	30 ≤ $\bar{x}$ of N_{vB} / 1000 ≤ 160? Yes [X] No [ ]					
			V_{c2}	84							

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; unc: Uncountable
As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 80% here.

Test Suspension and Testing

	N	V_{c1}	V_{c2}	
Test suspension (N and N_0)	10^{-5}	381	391	N = (381 + 391 + 56 + 47) / 2,2x10^{-5} = 7,6 log N_0 = N/10 = 6,6 log N_0 is between 6,17 and 6,70 Yes [X] No [ ]
	10^{-6}	56	47	

Concentration / Contact time	Dilution factor	V_{c1}	V_{c2}	N_a= $\bar{x}$ x10	*log* N_a	*log R* (N_0=6,54)
80 % 5 minutes	10^0	0*	0*	<140	<2,15	**>4,45**
	10^{-1}	0	0			
80 % 10 minutes	10^0	0*	0*	<140	<2,15	**>4,45**
	10^{-1}	0	0			
80 % 15 minutes	10^0	0*	0*	<140	<2,15	**>4,45**
	10^{-1}	0	0			
40 % 5 minutes	10^0	0*	0*	<140	<2,15	**>4,45**
	10^{-1}	0	0			
20 % 5 minutes	10^0	177*	178*	1968	3,29	3,31
	10^{-1}	39*	39*			

V_c: Number of CFUs counted/ml ; N: Number of CFUs in the test suspension ; N_0: Number of CFUs in the test mixture ; N_a: Number of CFUs counted after contact with the product ; N_{vo}: Number of CFUs/ml in the dilution of the validation suspension ; R: Reduction in the number of bacteria ; Unc: Uncountable

Control of weighted averages: D= [(381 + 391)/2] / [(56 + 47)/2] = 7,50
7,50 is between 5 and 15.

Remarks about the results

- ✓ All controls and the method validation mixture give values within the baseline limits.
- ✓ At least one concentration of the product showed a log reduction of at least 4 log.
- ✓ No precipitate formation during the test.

Conclusion

Tests were performed on strains referenced as *Candida albicans* IP 48.72 (Cf. Report 14-41) and *Aspergillus brasiliensis* I. P 1431.83.

The tests were carried out once. The reduction with the test strain *Aspergillus brasiliensis* in 5 minutes at 40% is $2{,}8.10^4$ or 4,45 log.

In accordance with standard **EN 13624 (2013)**, batch **4494** of **F010474V1,** when concentrated at **40%** (V/V) in **sterile distilled water** (Product used pure), shows **fungicidal** activity in **5 minutes** at **20°C**, under **clean conditions (BSA 0.3 g/l)**, with respect to the referenced strain *Aspergillus brasiliensis*, for disinfection of medical devices.

Clermont-Ferrand, le 28/01/2015

HYGIENE HOSPITALIERE
Centre de Biologie - 6ème Etage
CHU
63003 Clermont-Ferrand Cedex 1
Tél. : 04 73 754 870 - Fax : 04 73 754 871

TEST REPORT

YEASTICIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 14562 STANDARD

For: **FRANKLAB**
3 AVENUE DES FRENES
78180 MONTIGNY-LE-BRETONNEUX

Date of request: 07/17/2014

Study number: n°295D11-2014-05

YEASTICIDAL TESTS:

According to the European standard EN 14562 (September 2006) – Chemical disinfectants and antiseptics. Quantitative surface test for the evaluation of fungicidal or yeasticidal activity in the medical area (phase 2, step 2).

Tests using the F010474V1 product against 1 reference strain: *Candida albicans.*

This test report included 9 pages.

Study completion date: 12/29/2014

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

1. PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2. PRODUCT IDENTITY

SAMPLE	BATCH
F010474V1	4494

Expiration date: Non communicated

Manufacturer: FRANKLAB

Manufacturing date: 11/24/2014

Storage conditions: as recommended by the manufacturer.

Active substances: peracetic acid

Appearence of the product : liquid, colorless

Diluent recommended by the manufacturer: tap water

Date of receipt: 08/02/2014

Date of the study: from 12/27/2014 to 12/28/2014

3. EXPERIMENTAL CONDITIONS

Final concentrations of the product: 100% and 10%

Method: EN 14562

Exposure time: 5 min - 10 min – 15 min - 60 min

Temperature using during the assays: 20°C

Organic soil load: clean conditions, BSA 0,3 g/L.

Diluent used for the microbial suspensions: trypton salt solution, sterile.

Strain: *Candida albicans* CIP 48.72 batch 265.09-Institut Pasteur.

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

Stop solution: glass carriers in 10 ml of neutralizer [sodium thiosulfate 2%)

4. VALIDATIONS AND ASSAYS

See results sheets.

The **F010474V1** product is effective on the reference strain used, because the average of the log reduction is > 4 log:

- *C.albicans*, R > 4,40 from 100% concentration

5. CONCLUSION

According to the EN 14562 (September 2006), the assays performed with the F010474V1 product:

- **Demonstrated a yeasticidal activity when the F010474V1 product is used from the 100% concentration against the reference strain, for an exposure time of 5 minutes at 20°C, in clean conditions (BSA 0,3 g/L)**

SHEET OF RESULTS -TRIALS
Candida albicans

STANDARD: EN 14562, phase 2 step 2
PRODUCT : F010474V1
BATCH#: 4494

Dilution-neutralization ☒ pour plate method
spread plate method
☒ number of plates/ml : 1

Neutralizer: sodium thiosulfate 2%

Temperature: 20°C.

Organic soil load: BSA 0,3 g/l

Strain : *Candida albicans* CIP 48.72 batch 265.09

Temperature: 30°C ± 1°C

Study #295D11-2014-05 Date of test : 12/27/2014

Study director : Stéphanie MOROT-BIZOT Signature :

Diluent : sterile hard water

Appearance of the product : clear

Validation and controls

	Suspension of validation **Nv0**		Experimental conditions control **A**		Neutralization control **B**		Validation of the method **C**	
Vc1	51,0	$\bar{x}$	39,0	$\bar{x}$	33,0	$\bar{x}$	35,0	$\bar{x}$
Vc2	48,0	49,5	35,0	37,0	41,0	37,0	33,0	34,0
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A is ≥0,5 × $\bar{x}$ of Nv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ of Nv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ of Nv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Trial suspension and trials

Trial suspension (N)			log N
10^{-6}	263	255	8,42
10^{-7}	30	25	
8,17 ≤ N ≤ 8,70? x yes □ no			

Water control (Nw)			log Nw
10^{-4}	32	30	6,49
6,15 ≤ log Nw ≤ lg N-1,3? x yes □ no			

	TRIALS									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		10% 5 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	59	45
10^{-2}	0	0	0	0	0	0	0	0	5	6
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		3,72	
log R = log Nw - log Na	>4,35		>4,35		>4,35		>4,35		2,78	

Methodology:

- To be valid:
  - 1,5 X 10^{8} CFU/mL ≤ N ≤ 5 X 10^{8} CFU/mL
  - 8,17 ≤ LogN ≤ 8,70
  - 1,4 X 10^{6} CFU/mL ≤ Nw ≤ lg N-1,3
  - R ≥ 4 for a product to be yeasticide

In the following tables:

- VC: number of CFU per ml
- 1E–XX = 1 X 10^{-XX}
- N: number of CFU of the fungicidal suspension per mL
- Log N: decimal logarithm of the fungicidal suspension.
- Nw = water control (number of viable cells after exposure time with water).
- Na: number of viable cells after exposure time with the product.
- Log Na: decimal logarithm of Na.
- R = logarithmic reduction of the fungicidal suspension after exposure time with the product (log R = log Nw-log Na).

SHEET OF RESULTS -REPETITIONS
Candida albicans

STANDARD: EN 14562, phase 2 step 2
PRODUCT : F010474V1
BATCH#: 4494

Dilution-neutralization ☒ pour plate method
spread plate method
☒ number of plates/ml : 1

Neutralizer: sodium thiosulfate 2%

Temperature: 20°C.

Organic soil load: BSA 0,3 g/l

Strain : *Candida albicans* CIP 48.72 batch 265.09

Temperature: 30°C ± 1°C

Study #295D11-2014-05 Date of test : 12/27/2014

Study director : Stéphanie MOROT-BIZOT Signature :

Diluent : sterile hard water

Appearance of the product : clear

Validation and controls

	Suspension of validation **Nv0**		Experimental conditions control **A**		Neutralization control **B**		Validation of the method **C**	
Vc1	51,0	$\bar{x}$	44,0	$\bar{x}$	47,0	$\bar{x}$	40,0	$\bar{x}$
Vc2	48,0	49,5	41,0	42,5	50,0	48,5	37,0	38,5
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A is ≥0,5 × $\bar{x}$ of Nv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ of Nv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ of Nv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Trial suspension and trials

Trial suspension (N)			log N
10^{-6}	263	255	8,42
10^{-7}	30	25	
8,17 ≤ N ≤ 8,70? x yes □ no			

Water control (Nw)			log Nw
10^{-4}	37	40	6,59
6,15 ≤ log Nw ≤ lg N-1,3? x yes □ no			

	TRIALS									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		10% 5 min	
10^{0}	0	0	0	0	0	0	0	0	>330	>330
10^{-1}	0	0	0	0	0	0	0	0	43	39
10^{-2}	0	0	0	0	0	0	0	0	0	0
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		3,61	
log R = log Nw - log Na	>4,44		>4,44		>4,44		>4,44		2,97	

Methodology:
- To be valid:
  - 1,5 X 10^{8} CFU/mL ≤ N ≤ 5 X 10^{8} CFU/mL
  - 8,17 ≤ LogN ≤ 8,70
  - 1,4 X 10^{6} CFU/mL ≤ Nw ≤ lg N-1,3
  - R ≥ 4 for a product to be yeasticide

In the following tables:
- VC: number of CFU per ml
- 1E–XX = 1 X 10^{-XX}
- N: number of CFU of the fungicidal suspension per mL
- Log N: decimal logarithm of the fungicidal suspension.
- Nw = water control (number of viable cells after exposure time with water).
- Na: number of viable cells after exposure time with the product.
- Log Na: decimal logarithm of Na.
- R = logarithmic reduction of the fungicidal suspension after exposure time with the product (log R = log Nw-log Na).

6. TECHNICAL APPENDIX

MEDIA

MEA (Malt Extract Agar), Dominique DUTSCHER, ref. 777304, batch n° n°307171

ORGANIC SOIL LOAD :
BSA, Fraction V, SIGMA ALDRICH, ref. P6154, batch M10637P6154

DILUENT

Trypton-Salt Solution

Per liter of distilled water:

- Trypton, Dominique dutscher, ref. 777742, batch n°090633 ----------1,00 g
- Sodium Chloride, Grosseron, ref n°9020401, batch n° FR08 085 793----------8,50 g

Final pH at 25°C : 7,0 ± 0,2

NEUTRALIZER

Per liter of distilled water:

Sodium thiosulfate, SigmaAldrich ref: 72049; batch n°BCBD0584V ----------20 g

Sterilization on filter 0,45 µm ; pH à 25°C : 7,4 ± 0,1

GLASS CARRIERS – blades of frosted glass 15 x 60 mm, 1 mm thick – Thermo scientific/ Menzel-Gläser – ref. 100 OTM, batch #01 1794389.

HARD WATER

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

- CaCl2 anhydre, ref. C1016, batch n° 059K0030, SIGMA ALDRICH

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

pH: 7,0 ± 0,2 at 25°C.

FUNGICIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 14562 STANDARD

For: **FRANKLAB**
3 AVENUE DES FRENES
78180 MONTIGNY-LE-BRETONNEUX

Date of request: 11/20/2014

Study number: n°295D11-2014-05

FUNGICIDAL TESTS:

According to the European standard EN 14562 (September 2006) – Chemical disinfectants and antiseptics. Quantitative surface test for the evaluation of fungicidal or yeasticidal activity in the medical area (phase 2, step 2).

Tests using the F010474V1 product against 1 reference strain: *Aspergillus brasiliensis.*

This test report included 9 pages.

Study completion date: 12/31/2014

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

1. PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON

2. PRODUCT IDENTITY

SAMPLE	BATCH
F010474V1	4494

Expiration date: Non communicated

Manufacturer: FRANKLAB

Manufacturing date: Non communicated

Storage conditions: as recommended by the manufacturer.

Active substances: peracetic acid

Appearence of the product : liquid, colorless

Diluent recommended by the manufacturer: tap water

Date of receipt: 11/26/2014

Date of the study: from 12/29/2014 to 12/31/2014

3. EXPERIMENTAL CONDITIONS

Final concentrations of the product: 100% and 10%

Method: EN 14562

Exposure time: 5 min - 10 min – 15 min - 60 min

Temperature using during the assays: 20°C

Organic soil load: clean conditions, BSA 0,3 g/L.

Diluent used for the microbial suspensions: trypton salt solution, sterile.

Strain: *Aspergillus brasiliensis* CIP1431.83 batch n°252.09 (ATCC 16404)-Institut Pasteur.

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

Stop solution: glass carriers in 10 ml of neutralizer [sodium thiosulfate 2%)

4. VALIDATIONS AND ASSAYS

See results sheets.

The **F010474V1** product is effective on the reference strain used, because the average of the log reduction is > 4 log:

- *A.brasiliensis*, R > 4,05 from 100% concentration

5. CONCLUSION

According to the EN 14562 (September 2006), the assays performed with the F010474V1 product:

- **Demonstrated a fungicidal activity when the F010474V1 product is used from the 100% concentration against the reference strain, for an exposure time of 5 minutes at 20°C, in clean conditions (BSA 0,3 g/L)**

SHEET OF RESULTS -TRIALS
Aspergillus brasiliensis

STANDARD: EN 14562, phase 2 step 2
PRODUCT : F010474V1
BATCH#: 4494

Dilution-neutralization ☒ pour plate method
spread plate method
☒ number of plates/ml : 1

Neutralizer: sodium thiosulfate 2%

Temperature: 20°C.

Organic soil load: BSA 0,3 g/l

Strain : *Aspergillus brasiliensis* CIP1431.83 (ATCC 16404)

Temperature: 30°C ± 1°C

Study #295D11-2014-05 Date of test : 12/29/2014

Study director : Stéphanie MOROT-BIZOT Signature :

Diluent : sterile hard water

Appearance of the product : clear

Validation and controls

	Suspension of validation **Nv0**		Experimental conditions control **A**		Neutralization control **B**		Validation of the method **C**	
Vc1	32,0	$\bar{x}$	40,0	$\bar{x}$	45,0	$\bar{x}$	40,0	$\bar{x}$
Vc2	36,0	34,0	38,0	39,0	44,0	44,5	40,0	40,0
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A is ≥0,5 × $\bar{x}$ of Nv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ of Nv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ of Nv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Trial suspension and trials

Trial suspension (N)			log N
10^{-7}	159	147	8,19
10^{-8}	15	17	
8,17 ≤ N ≤ 8,70? x yes □ no			

Water control (Nw)			log Nw
10^{-3}	142	153	6,17
6,15 ≤ log Nw ≤ lg N-1,3? x yes □ no			

	TRIALS									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		10% 5 min	
10^{0}	0	0	0	0	0	0	0	0	>165	>165
10^{-1}	0	0	0	0	0	0	0	0	>165	>165
10^{-2}	0	0	0	0	0	0	0	0	15	17
10^{-3}	0	0	0	0	0	0	0	0	0	1
log Na	<2,15		<2,15		<2,15		<2,15		>4,20	
log R = log Nw - log Na	**>4,02**		**>4,02**		**>4,02**		**>4,02**		<2,97	

Methodology:
- To be valid:
  - 1,5 X 10^{8} CFU/mL ≤ N ≤ 5 X 10^{8} CFU/mL
  - 8,17 ≤ LogN ≤ 8,70
  - 1,4 X 10^{6} CFU/mL ≤ Nw ≤ lg N-1,3
  - R ≥ 4 for a product to be yeasticide

In the following tables:
- VC: number of CFU per ml
- 1E–XX = 1 X 10^{-XX}
- N: number of CFU of the fungicidal suspension per mL
- Log N: decimal logarithm of the fungicidal suspension.
- Nw = water control (number of viable cells after exposure time with water).
- Na: number of viable cells after exposure time with the product.
- Log Na: decimal logarithm of Na.
- R = logarithmic reduction of the fungicidal suspension after exposure time with the product (log R = log Nw-log Na).

SHEET OF RESULTS - REPETITIONS
Aspergillus brasiliensis

STANDARD: EN 14562, phase 2 step 2
PRODUCT : F010474V1
BATCH#: 4494

Dilution-neutralization ☒ pour plate method
spread plate method
☒ number of plates/ml : 1

Neutralizer: sodium thiosulfate 2%

Temperature: 20°C.

Organic soil load: BSA 0,3 g/l

Strain : *Aspergillus brasiliensis* CIP1431.83 (ATCC 16404)

Temperature: 30°C ± 1°C

Study #295D11-2014-05 Date of test : 12/29/2014

Study director : Stéphanie MOROT-BIZOT Signature :

Diluent : sterile hard water

Appearance of the product : clear

Validation and controls

	Suspension of validation **Nv0**		Experimental conditions control **A**		Neutralization control **B**		Validation of the method **C**	
Vc1	32,0	$\bar{x}$	45,0	$\bar{x}$	40,0	$\bar{x}$	33,0	$\bar{x}$
Vc2	36,0	34,0	39,0	42,0	38,0	39,0	35,0	34,0
	30 ≤ $\bar{x}$ of Nv0 ≤160		$\bar{x}$ of A is ≥0,5 × $\bar{x}$ of Nv0		$\bar{x}$ of B ≥ 0,5× $\bar{x}$ of Nv0		$\bar{x}$ of C ≥ 0,5 × $\bar{x}$ of Nv0	
	x yes □ no		x yes □ no		x yes □ no		x yes □ no	

Trial suspension and trials

Trial suspension (N)			log N
10^{-7}	159	147	8,19
10^{-8}	15	17	
8,17 ≤ N ≤ 8,70? x yes □ no			

Water control (Nw)			log Nw
10^{-3}	166	173	6,23
6,15 ≤ log Nw ≤ lg N-1,3? x yes □ no			

	TRIALS									
	100% 5 min		100% 10 min		100% 15 min		100% 60 min		10% 5 min	
10^{0}	0	0	0	0	0	0	0	0	>165	>165
10^{-1}	0	0	0	0	0	0	0	0	>165	>165
10^{-2}	0	0	0	0	0	0	0	0	12	14
10^{-3}	0	0	0	0	0	0	0	0	0	0
log Na	<2,15		<2,15		<2,15		<2,15		>4,11	
log R = log Nw - log Na	**>4,08**		**>4,08**		**>4,08**		**>4,08**		<3,12	

Methodology:
- To be valid:
  - 1,5 X 10^{8} CFU/mL ≤ N ≤ 5 X 10^{8} CFU/mL
  - 8,17 ≤ LogN ≤ 8,70
  - 1,4 X 10^{6} CFU/mL ≤ Nw ≤ lg N-1,3
  - R ≥ 4 for a product to be yeasticide

In the following tables:
- VC: number of CFU per ml
- 1E–XX = 1 X 10^{-XX}
- N: number of CFU of the fungicidal suspension per mL
- Log N: decimal logarithm of the fungicidal suspension.
- Nw = water control (number of viable cells after exposure time with water).
- Na: number of viable cells after exposure time with the product.
- Log Na: decimal logarithm of Na.
- R = logarithmic reduction of the fungicidal suspension after exposure time with the product (log R = log Nw-log Na).

6. TECHNICAL APPENDIX

MEDIA

MEA (Malt Extract Agar), Dominique DUTSCHER, ref. 777304, batch n° n°307171

ORGANIC SOIL LOAD :
BSA, Fraction V, SIGMA ALDRICH, ref. 05479, batch STBB7838V

DILUENT

Trypton-Salt Solution

Per liter of distilled water:

- Trypton, Dominique dutscher, ref. 777742, batch n°090633 ----------1,00 g
- Sodium Chloride, Grosseron, ref n°9020401, batch n° FR08 085 793----------8,50 g

Final pH at 25°C : 7,0 ± 0,2

NEUTRALIZER

Per liter of distilled water:

Sodium thiosulfate, SigmaAldrich ref: 72049; batch n°BCBD0584V ----------20 g

Sterilization on filter 0,45 µm ; pH à 25°C : 7,4 ± 0,1

GLASS CARRIERS – blades of frosted glass 15 x 60 mm, 1 mm thick – Thermo scientific/ Menzel-Gläser – ref. 100 OTM, batch #01 1794389.

HARD WATER

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

- CaCl2 anhydre, ref. C1016, batch n° 059K0030, SIGMA ALDRICH

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

pH: 7,0 ± 0,2 at 25°C.

TEST REPORT

VIRUCIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 14476:2013 STANDARD

Delivered to : **Ms CHAKCHOUK**

For: **FRANKLAB**
3 AVENUE DES FRENES
78180 MONTIGNY-LE-BRETONNEUX

Date of request: 08/01/2014

Study references: n°295D11-2014-07

VIRUCIDAL TESTS:

According to the NF EN 14476 standard (September 2013) – chemical antiseptics and disinfectants – virucidal quantitative suspension tests for chemical disinfectants and antiseptics used in medical area.

Tests using the F010474V1 product against the adenovirus.

This test report included 10 pages.

Study completion date: 01/31/2015

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

F010474V1

Batch: n° 4494

Expiration date: non communicated

Manufacturer: FRANKLAB

Manufacturing date: non communicated

Storage conditions: as recommended by the manufacturer.

Active substances: peracetic acid

Appearence of the product : clear liquid, colorless

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

Date of receipt: 11/26/2014

Date of the study: from 12/06/2014 to 01/15/2015

3 EXPERIMENTAL CONDITIONS

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

Titration method: virus titered in log $TCID_{50}$.

Exposure Time: 5 minutes, 10 minutes and 15 min

Tested concentrations (final concentrations): 80%

Diluent used for the product: sterile distilled water

Viral strain: adenovirus type 5 adenoid 75 strain (ATCC VR5), grown on HEp-2 cells, at 37°C, under 5% CO2 atmosphere

Organic soil load: BSA 0,3 g/L (clean conditions)

Product stability: stable

Stop solution: cold shock

Viral titer:

Viral titer of the viruses, expressed in $TCID_{50}$, according to the Spearman-Kärber method:

- For adenovirus, titer = 7,50 log $TCID_{50}$.

4 VALIDATIONS

a) Cytotoxicity

For the F010474V1 product, the HEp-2 cells toxicity was observed until to the dilution 10^{-2}.

b) Cells sensitivity to the virus

The viruses were titrated on cell cultures untreated with the product (indicator cell line) and titrated on cell cultures treated with the product. According to the European standard EN 14476, the F010474V1 product does not have an effect on the viruses titration method (the difference between viral titers must be < 1,0 log):

		Viral titer (log $TCID_{50}$)		
Dilution		Untreated cell cultures	Treated cell cultures	**Difference**
F010474V1	10^{-3}	7,000	6,625	**0,375**

c) VALIDATIONS OF THE COLD SHOCK METHOD

Concentration		**Organic soil load**	**Viral titer (log $TCID_{50}$)**	**Difference with the viral suspension**
F010474V1	80%	0,3 g/l BSA	TRIAL 1: 7,500	0,000
			TRIAL 2: 7,500	0,000

The method is validated if the difference is ≤ 0,5 log.

d) INACTIVATION ASSAYS OF THE VIRUS WITH A CONTROL SOLUTION

The viral titer reduction (difference between the titers of the viral suspension treated with 0,7 % formaldehyde and the viral suspension control) must be between:

- -0.5 and -2,5 log after 30 min

Formaldehyde 0,7%	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction (log $TCID_{50}$)**
Viral suspension control	7,500	
Inactivation 5 min	7,500	0,125
Inactivation 15 min	6,250	1,375
Inactivation 30 min	5,500	**2,000**

5 VIRUCIDAL ASSAYS

The concentrations of the product demonstrated a virucidal activity on the virus tested if the viral titer reduction is ≥ 4,0 log.

TRIAL 1 – The viral suspension was titrated at 7,500 log $TCID_{50}$.

PRODUCT	**Concentration (v/v)**	**Time of exposure**	**Temperature**	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction**
F010474V1	80%	5 min	20°C	3,375	**4,125**
		10 min		3,125	**4,375**
		15 min		3,000	**4,500**

TRIAL 2 - The viral suspension was titrated at 7,500 log $DICT_{50}$.

PRODUCT	**Concentration (v/v)**	**Time of exposure**	**Temperature**	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction**
F010474V1	80%	5 min	20°C	3,500	**4,000**
		10 min		3,250	**4,250**
		15 min		2,875	**4,625**

6 VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 14476+A2:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product:
  - 7,500 log $TCID_{50}$ for adenovirus
- The virus was inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure:
  - the reduction observed was of 2,00 log for the adenovirus.
- The F010474V1 product does not have a cytotoxic effect on the HEp-2 cells.
- The F010474V1 product does not affect the infectious capacity of the viruses:
  - For adenovirus, the differences in viral titers between the virus inoculated on HEp-2 cells and the virus inoculated on the HEp-2 cells treated with the product was ≤ 1,0 log (0,375 log).

7 CONCLUSION

The assays performed with the F010474V1 product:

- **Demonstrated a virucidal activity on the adenovirus from the concentration 80%,** as required by the European standard EN 14476, following a **5 min** exposure period, at 20°C, in clean conditions.

8 TECHNICAL APPENDIX 1

Cell line: HEp-2 cells (RD-Biotech ref. 84011, batch n°110315-118)

Viral strain: adenovirus type 5, adenoïd 75 strain (ATCC ref. VR-5, batch n°3679877)

Buffer and reagents:

- Buffer PBS 10X: Dutscher, réf. 091591, batch n° 903711
- DMEM media, Dutscher, réf. P04-03590, batch n° 6580314
- Calf serum, Sigma Aldrich, ref. F7524, lot n° 078K3396

Organic soil load:

- Bovine Sera Albumin, Dutscher, ref. P6154, batch n° M10637P6154

Inactivation solution: Formaldehyde, Sigma Aldrich, ref. F-1635, batch n° BCBB3510

9 TECHNICAL APPENDIX 2

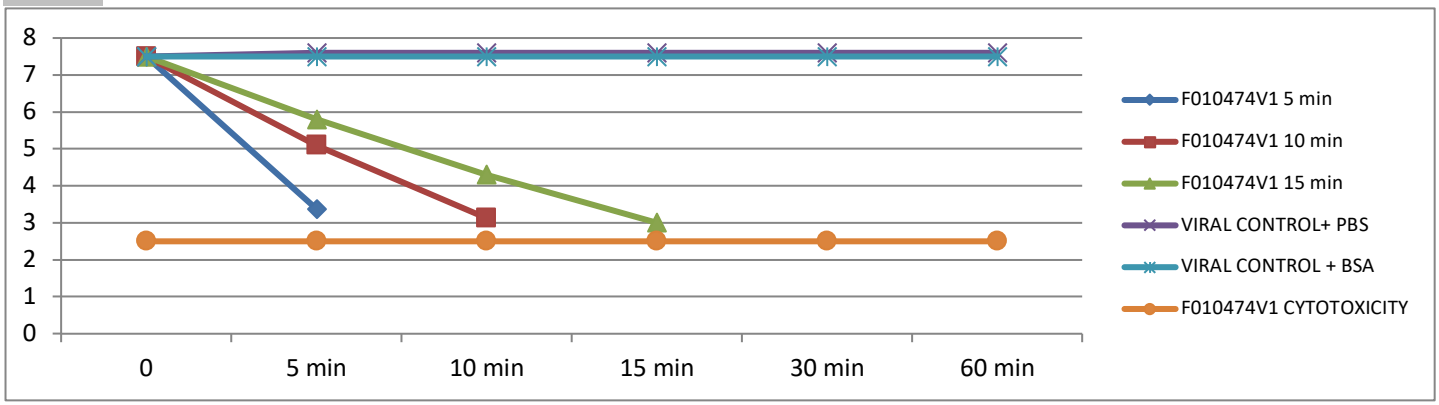
Table A1 – Adenovirus titer by Spaerman-Kärber method:

log $DICT_{50}$ = 7,50

Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	21222111	100
-7	11111111	100
-8	00000000	0
-9	00000000	0
-10	00000000	0
Sum of the % of positives cultures		500

Chart 1 – Trials on adenovirus:

TRIAL 1



TRIAL 2

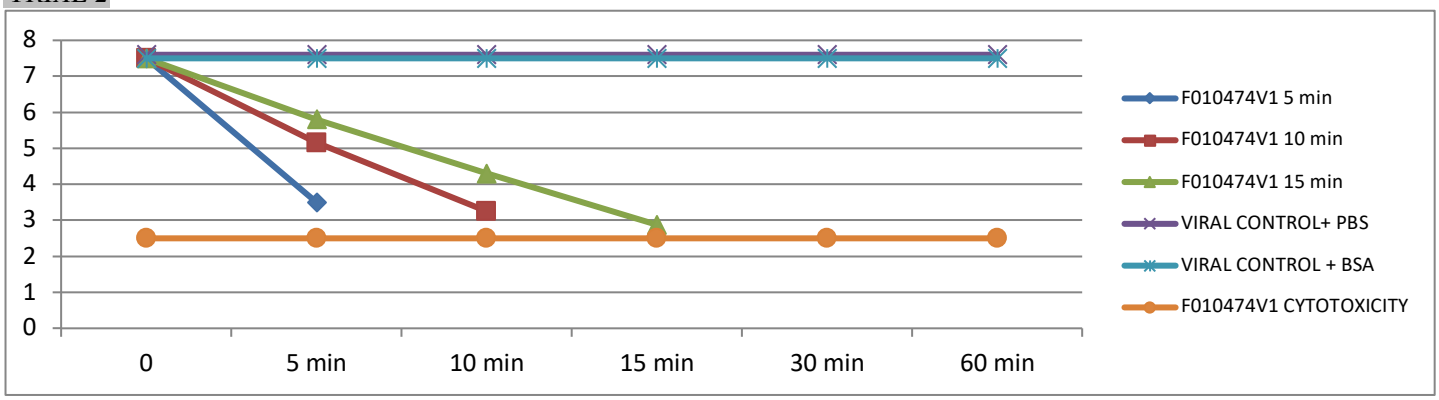


Table A2 — Results on adenovirus in clean conditions

PRODUCT	CONCENTRATION	ORGANIC SOIL LOAD	CYTOTOXICITY LEVEL	Lg $DICT_{50}$						Reduction
				0	5 min	10 min	15 min	30 min	60 min	
F010474V1 TRIAL 1	80,00%	0,3 g/l BSA	2,5	7,5	3,375	3,125	3	N.T.	N.T.	R 5 min = 4,125 R 10 min=4,375 R 15 min = 4,5
F010474V1 TRIAL 2	80,00%	0,3 g/l BSA	2,5	7,5	3,5	3,25	2,875	N.T.	N.T.	R 5 min = 4,00 R 10 min=4,25 R 15 min = 4,625
Formaldéhyde	1,40%	PBS	2,375	7,5	7,5	N.T.	N.T.	6,25	5,5	
VIRAL CONTROL OF INFECTIVITY Trial 1	N.A.	PBS	N.A	7,5	N.T.	N.T.	N.T.	N.T.	7,5	
	N.A.	0,3 g/l BSA	N.A	7,5	N.T.	N.T.	N.T.	N.T.	7,5	
VIRAL CONTROL OF INFECTIVITY Trial 2	N.A.	PBS	N.A	7,5	N.T.	N.T.	N.T.	N.T.	7,5	
	N.A.	0,3 g/l BSA	N.A	7,5	N.T.	N.T.	N.T.	N.T.	7,5	
CELL SENSITIVITY TO THE VIRUS	F010474V1	N.A.	UNTREATED CELLS	N.T.	N.T.	N.T.	N.T.	N.T.	7,5	
	10^{-3}	N.A.	TREATED CELLS	N.T.	N.T.	N.T.	N.T.	N.T.	7,125	

Table A3 — Raw results for trial 1

TRIAL 1

	Concentration	Organic soil load	Contact time	Dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1 TRIAL 1	80,00%	0,3 g/l BSA	5 min	4444	4433	1111	0000	0000	0000	0000	0000
				4444	3333	1110	0000	0000	0000	0000	0000
			10 min	4444	4444	1100	0000	0000	0000	0000	0000
				4444	4444	1111	0000	0000	0000	0000	0000
			15 min	4444	4444	1211	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			VIRAL CONTROL	4444	4444	3333	2212	1111	1111	1111	0000
				4444	4444	3333	2111	1111	1111	1111	0000
F010474V1 TRIAL 1 cytotoxicity	80,00%	0,3 g/l BSA	N.A.	4444	3233	0000	0000	0000	0000	0000	0000
				4444	2222	0000	0000	0000	0000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	2222	1111	1111	1111	1111	0000
				4444	4444	2322	1111	1111	1111	1111	0000
			60	4444	4444	3332	1111	1111	1111	1111	0000
				4444	4444	2322	1111	1111	1111	1111	0000
	N.A.	0,3 g/l BSA	0	4444	4444	3333	2212	1111	1111	1111	0000
				4444	4444	3333	2222	1111	1111	1111	0000
			60	4444	4444	2222	2222	1111	1111	1111	0000
				4444	4444	3333	2222	1111	1111	1111	0000
Formaldehyde	1,40%		5	4444	4444	4444	3333	2222	1111	0111	1000
				4444	4444	4444	3333	2222	1111	1111	0000
			15	4444	4444	4444	3333	1222	1111	0000	0000
				4444	4444	4444	2222	1111	1100	0000	0000
			30	4444	4444	4444	2121	1111	0000	0000	0000
				4444	4444	4444	1111	1111	0000	0000	0000
Formaldehyde (cytotoxicity)	1,40%		N.A.	4444	1011	0000	0000	N.T.	N.T.	N.T.	N.T.
				4444	1111	0000	0000				

TRIAL 2

	Concentration	Organic soil load	Contact time	Dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1 TRIAL 2	80,00%	0,3 g/l BSA	5 min	4444	4444	1111	0000	0000	0000	0000	0000
				4444	4444	1111	0000	0000	0000	0000	0000
			10 min	4444	4433	1100	0000	0000	0000	0000	0000
				4444	3222	1111	0000	0000	0000	0000	0000
			15 min	4444	3333	2110	0000	0000	0000	0000	0000
				4444	3334	0000	0000	0000	0000	0000	0000
			VIRAL CONTROL	4444	4444	3333	1111	1111	1111	1111	0000
				4444	4444	2222	1111	1111	1111	1111	0000
F010474V1 TRIAL 2 cytotoxicity	80,00%	0,3 g/l BSA	N.A.	4444	3333	0000	0000	0000	0000	0000	0000
				4444	3333	0000	0000	0000	0000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	2222	1111	1111	1111	1111	0000
				4444	4444	2222	1111	1111	1111	0111	0000
			60	4444	4444	3332	1111	1111	1111	1111	0000
				4444	4444	3322	1111	1111	1111	1111	0000
	N.A.	0,3 g/l BSA	0	4444	4444	3333	2222	1111	1111	1111	0000
				4444	4444	3333	2222	1111	1111	1111	0000
			60	4444	4444	3333	2222	1111	1111	1111	0000
				4444	4444	3333	2222	1111	1111	1111	0000
Formaldehyde	1,40%		5	4444	4444	4444	3333	3322	1111	1111	0000
				4444	4444	4444	3333	1222	1111	1111	0000
			15	4444	4444	4444	3333	1222	1111	0000	0000
				4444	4444	4444	2222	1111	0000	0000	0000
			30	4444	4444	4444	1100	0000	0000	0000	0000
				4444	4444	4444	0000	0000	0000	0000	0000
Formaldehyde (cytotoxicity)	1,40%		N.A.	4444	2221	0000	0000	N.T.	N.T.	N.T.	N.T.
				4444	1111	0000	0000				

Cells sensitivity to the virus :

Product	Dilution	Organic soil load		Dilutions						
				-2	-3	-4	-5	-6	-7	-8
F010474V1	10^{-3}	0,3 g/l BSA	Untreated cells	4444	4444	2222	1111	1111	1111	0000
				4444	4444	1211	1111	1111	1111	0000
			Treated cells	4444	4444	1222	1 111	1111	1111	0000
				4444	4444	2222	1111	1111	1000	0000

Validations with other concentration:

	Concentration	Organic soil load	Contact time	dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1	50,00%	0,3 g/l BSA	5 min	4444	4444	2222	1111	1111	0000	0000	0000
				4444	4444	2222	1111	0000	0000	0000	0000

	Concentration	Organic soil load	Contact time	Log $TCID_{50}$		Re-duction	
				0	5 min		
F010474V1	50,00%	0,3 g/l BSA	5 min	7,125	5,000	2,125	inactive

TEST REPORT

VIRUCIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 14476:2013 STANDARD

Delivered to : **Ms CHAKCHOUK**

For: **FRANKLAB**
3 AVENUE DES FRENES
78180 MONTIGNY-LE-BRETONNEUX

Date of request: 05/22/2015

Study references: n°140D10-2015-02

VIRUCIDAL TESTS:

According to the NF EN 14476 standard (September 2013) – chemical antiseptics and disinfectants – virucidal quantitative suspension tests for chemical disinfectants and antiseptics used in medical area.

Tests using the F010474V1 product against the norovirus.

This test report included 10 pages.

Study completion date: 01/23/2016

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

F010474V1

Batch: n° 4494B01

Expiration date: non communicated

Manufacturer: FRANKLAB

Manufacturing date: non communicated

Storage conditions: as recommended by the manufacturer.

Active substances: peracetic acid

Appearence of the product : clear liquid, colorless

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

Date of receipt: 05/22/2015

Date of the study: from 06/26/2015 to 08/20/2015

3 EXPERIMENTAL CONDITIONS

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

Titration method: virus titered in log $TCID_{50}$.

Exposure Time: 5 minutes, 10 minutes and 15 min

Tested concentrations (final concentrations): 80%

Diluent used for the product: sterile distilled water

Viral strain: norovirus murin MNV-1, strain S99, grown on RAW 264.7 cells, at 37°C, under 5% CO2 atmosphere

Organic soil load: BSA 0,3 g/L (clean conditions)

Product stability: stable

Stop solution: cold shock

Viral titer:

Viral titer of the viruses, expressed in $TCID_{50}$, according to the Spearman-Kärber method:

- For norovirus, titer = 7,50 log $TCID_{50}$.

4 VALIDATIONS

a) Cytotoxicity

For the F010474V1 product, the RAW cells toxicity was observed until to the dilution 10^{-2}.

b) Cells sensitivity to the virus

The viruses were titrated on cell cultures untreated with the product (indicator cell line) and titrated on cell cultures treated with the product. According to the European standard EN 14476+A2, the F010474V1 product does not have an effect on the viruses titration method (the difference between viral titers must be < 1,0 log):

		Viral titer (log $TCID_{50}$)		
Dilution		Untreated cell cultures	Treated cell cultures	**Difference**
F010474V1	10^{-3}	7,000	6,625	**0,375**

c) VALIDATIONS OF THE COLD SHOCK METHOD

Concentration	**Organic soil load**	**Viral titer (log $TCID_{50}$)**	**Difference with the viral suspension**
F010474V1 80%	0,3 g/l BSA	TRIAL 1: 7,375	0,125
		TRIAL 2: 7,250	0,250

The method is validated if the difference is ≤ 0,5 log.

d) INACTIVATION ASSAYS OF THE VIRUS WITH A CONTROL SOLUTION

The viral titer reduction (difference between the titers of the viral suspension treated with 0,7 % formaldehyde and the viral suspension control) must be between:

- -0.5 and -2,5 log after 30 min

Formaldehyde 0,7%	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction (log $TCID_{50}$)**
Viral suspension control	7,500	
Inactivation 5 min	7,000	0,500
Inactivation 15 min	6,125	1,375
Inactivation 30 min	5,500	**2,000**

5 VIRUCIDAL ASSAYS

The concentrations of the product demonstrated a virucidal activity on the virus tested if the viral titer reduction is ≥ 4,0 log.

TRIAL 1 – The viral suspension was titrated at 7,500 log $TCID_{50}$.

PRODUCT	**Concentration (v/v)**	**Time of exposure**	**Temperature**	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction**
F010474V1	80%	5 min	20°C	3,375	**4,125**
		10 min		3,000	**4,500**
		15 min		2,500	**5,000**

TRIAL 2 - The viral suspension was titrated at 7,125 log $DICT_{50}$.

PRODUCT	**Concentration (v/v)**	**Time of exposure**	**Temperature**	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction**
F010474V1	80%	5 min	20°C	2,875	**4,250**
		10 min		2,750	**4,375**
		15 min		2,500	**4,625**

6 VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 14476+A2:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product:
  - 7,500 log $TCID_{50}$ for norovirus
- The virus was inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure:
  - the reduction observed was of 2,00 log for the norovirus.
- The F010474V1 product does not have a cytotoxic effect on the RAW cells.
- The F010474V1 product does not affect the infectious capacity of the viruses:
  - For norovirus, the differences in viral titers between the virus inoculated on RAW cells and the virus inoculated on the RAW cells treated with the product was ≤ 1,0 log (0,375 log).

7 CONCLUSION

The assays performed with the F010474V1 product:

- **Demonstrated a virucidal activity on the norovirus from the concentration 80%,** as required by the European standard EN 14476, following a **5 min** exposure period, at 20°C, in clean conditions.

8 TECHNICAL APPENDIX 1

Cell line: RAW 264.7 cells (ATCC TIB-71)

Viral strain: norovirus murin, S99 strain (batch n° 4/200409/220409- Friedrich Loeffler Institut)

Buffer and reagents:

- Buffer PBS 10X: Dutscher, réf. 091591, batch n° 903711
- DMEM media, Dutscher, réf. P04-03590, batch n° 6580314
- Calf serum, Sigma Aldrich, ref. F7524, lot n° 078K3396

Organic soil load:

- Bovine Sera Albumin, Dutscher, ref. P6154, batch n° M10637P6154

Inactivation solution: Formaldehyde, Sigma Aldrich, ref. F-1635, batch n° BCBB3510

9 TECHNICAL APPENDIX 2

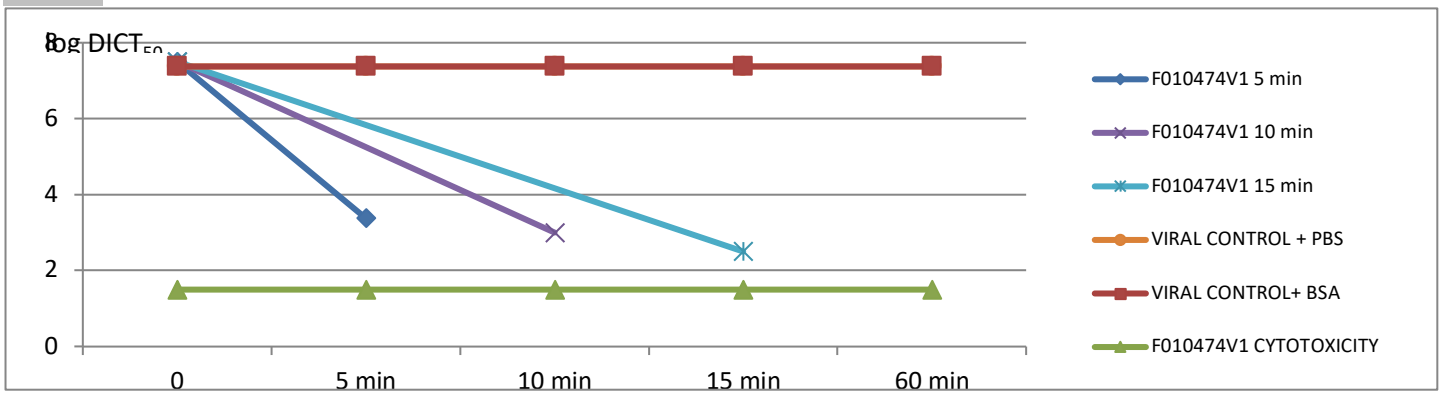
Table A1 – norovirus titer by Spaerman-Kärber method:

log $DICT_{50}$ = 7,50

Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	21222111	100
-7	11111111	100
-8	00000000	0
-9	00000000	0
-10	00000000	0
Sum of the % of positives cultures		500

Chart 1 – Trials on norovirus:

TRIAL 1



TRIAL 2

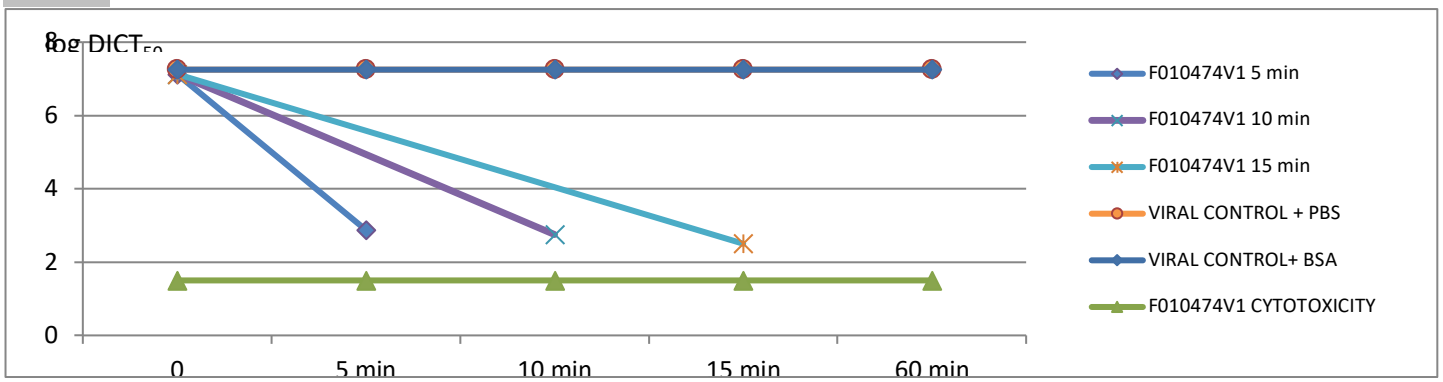


Table A2 — Results on norovirus in clean conditions

PRODUCT	CONCENTRATION	ORGANIC SOIL LOAD	CYTOTOXICITY LEVEL	Lg $DICT_{50}$					Reduction
				0	5 min	10 min	15 min	60 min	
F010474V1 TRIAL 1	80,00%	0,3 g/l BSA	1,5	7,5	3,375	3,0	2,5	N.T.	R 5 min = 4,125 R 10 min = 4,5 R 15 min = 5,0
F010474V1 TRIAL 2	80,00%	0, 3 g/l BSA	1,5	7,125	2,875	2,75	2,5	N.T.	R 5 min = 4,25 R 10 min = 4,375 R 15 min = 4,625
Formaldehyde	1,40%	PBS	2,5	7,5	7,0	6,125	5,5	N.T.	
VIRAL CONTROL OF INFECTIVITY Trial 1	N.A.	PBS	N.A	7,375	N.T.	N.T.	N.T.	7,375	
	N.A.	0, 3 g/l BSA	N.A	7,375	N.T.	N.T.	N.T.	7,375	
VIRAL CONTROL OF INFECTIVITY Trial 2	N.A.	PBS	N.A	7,25	N.T.	N.T.	N.T.	7,25	
	N.A.	0, 3 g/l BSA	N.A	7,25	N.T.	N.T.	N.T.	7,25	
CELL SENSITIVITY TO THE VIRUS	F010474V1	N.A.	UNTREATED CELLS	N.T.	N.T.	N.T.	N.T.	7,0	
	10^{-3}	N.A.	TREATED CELLS	N.T.	N.T.	N.T.	N.T.	6,625	

Table A3 — Raw results for trial 1

TRIAL 1

	Concentration	Organic soil load	Contact time	Dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1 TRIAL 1	80,00%	0,3 g/l BSA	5 min	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4440	0000	0000	0000	0000	0000
			10 min	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			15 min	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			VIRAL CONTROL	4444	4444	4444	4444	2111	1111	1111	0000
				4444	4444	4444	4444	2111	1111	1111	0000
F010474V1 TRIAL 1 cytotoxicity	80,00%	0,3 g/l BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	2211	1111	1111	0000
				4444	4444	4444	4444	1111	1111	1110	0000
			60	4444	4444	4444	4444	2221	1111	1111	0000
				4444	4444	4444	4444	2222	1111	1110	0000
	N.A.	0,3 g/l BSA	0	4444	4444	4444	4444	2122	1111	1111	0000
				4444	4444	4444	4444	3222	1111	1110	0000
			60	4444	4444	4444	4444	2332	1111	1111	0000
				4444	4444	4444	4444	2333	1111	1110	0000
Formaldehyde	1,40%		5	4444	4444	4444	4444	2111	1111	1110	0000
				4444	4444	4444	4444	1111	1111	1000	0000
			15	4444	4444	4444	1111	1111	1111	0000	0000
				4444	4444	4444	1111	1111	1000	0000	0000
			30	4444	4444	4444	1111	1111	0000	0000	0000
				4444	4444	4444	2111	1111	0000	0000	0000
Formaldehyde (cytotoxicity)	1,40%		N.A.	4444	1111	0000	0000	N.T.	N.T.	N.T.	N.T.
				4444	1111	0000	0000				

TRIAL 2

	Concentration	Organic soil load	Contact time	Dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1 TRIAL 2	80,00%	0,3 g/l BSA	5 min	4444	4444	4440	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			10 min	4444	4444	4400	0000	0000	0000	0000	0000
				4444	4444	000	0000	0000	0000	0000	0000
			15 min	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			VIRAL CONTROL	4444	4444	4444	4444	2222	1111	1111	0000
				4444	4444	4444	4444	2222	1111	1111	0000
F010474V1 TRIAL 2 cytotoxicity	80,00%	0,3 g/l BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	2212	1111	1010	0000
				4444	4444	4444	4444	2222	1111	1111	0000
			60	4444	4444	4444	4444	1111	1111	1111	0000
				4444	4444	4444	4444	1111	1111	1100	0000
	N.A.	0,3 g/l BSA	0	4444	4444	4444	4444	1111	1111	1111	0000
				4444	4444	4444	4444	1111	1111	1100	0000
			60	4444	4444	4444	4444	1111	1111	1111	0000
				4444	4444	4444	4444	1111	1111	1100	0000
Formaldehyde	1,40%		5	4444	4444	4444	2112	1111	1111	1000	0000
				4444	4444	4444	1111	1111	1111	1111	0000
			15	4444	4444	4444	1111	1111	1100	0000	0000
				4444	4444	4444	1111	1111	1000	0000	0000
			30	4444	4444	4444	1111	1111	1000	0000	0000
				4444	4444	4433	1111	1111	0000	0000	0000
Formaldehyde (cytotoxicity)	1,40%		N.A.	4444	1111	0000	0000	N.T.	N.T.	N.T.	N.T.
				4444	1110	0000	0000				

Cells sensitivity to the virus :

Product	Dilution	Organic soil load		Dilutions						
				-2	-3	-4	-5	-6	-7	-8
F010474V1	10^{-3}	0,3 g/l BSA	Untreated cells	4444	4444	4444	2212	1111	1111	0000
				4444	4444	4444	2232	1111	1111	0000
			Treated cells	4444	4444	3222	1 222	1111	1000	0000
				4444	4444	2222	1111	1111	0000	0000

Validations with other concentration:

	Concentration	Organic soil load	Contact time	dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1	50,00%	0,3 g/l BSA	5 min	4444 4444	4444 4444	4444 4444	4444 4444	1111 1111	1100 0000	0000 0000	0000 0000

	Concentration	Organic soil load	Contact time	Log $TCID_{50}$		Re-duction	
				0	5 min		
F010474V1	50,00%	0,3 g/l BSA	5 min	7	5,75	1,25	inactive

TEST REPORT

VIRUCIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 14476+A2 :2015 STANDARD

Delivered to : **Ms CHAKCHOUK**

For: **FRANKLAB**
3 AVENUE DES FRENES
78180 MONTIGNY-LE-BRETONNEUX

Date of request: 04/12/2017

Study references: n°061D04-2017-21

VIRUCIDAL TESTS:

According to the NF EN 14476+A2 standard (October 2015) – chemical antiseptics and disinfectants – virucidal quantitative suspension tests for chemical disinfectants and antiseptics used in medical area.

Tests using the F010474V1 product against the poliovirus.

This test report included 10 pages.

Study completion date: 08/31/2017

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
4 RUE DES GRANDES PIECES
25 770 SERRE LES SAPINS

2 PRODUCT IDENTITY

F010474V1

Batch: n° 5614

Expiration date: non communicated

Manufacturer: FRANKLAB

Manufacturing date: non communicated

Storage conditions: as recommended by the manufacturer.

Active substances: peracetic acid

Appearence of the product : clear liquid, colorless

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

Date of receipt: 04/18/2017

Date of the study: from 07/02/2017 to 08/30/2017

3 EXPERIMENTAL CONDITIONS

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

Titration method: virus titered in log $TCID_{50}$.

Exposure Time: 5 minutes, 10 minutes and 60 min

Tested concentrations (final concentrations): 80%

Diluent used for the product: sterile hard water

Viral strain: Poliovirus type 1, LSc-2ab strain (ATCC VR-59), grown on LLC-MK2 cells,at 37°C, under 5% CO2 atmosphere

Organic soil load: BSA 0,3 g/L (clean conditions)

Product stability: stable

Stop solution: cold shock

Viral titer:

Viral titer of the viruses, expressed in $TCID_{50}$, according to the Spearman-Kärber method:

- For POLIOVIRUS, titer = 7,75 log $TCID_{50}$.

4 VALIDATIONS

a) Cytotoxicity

For the F010474V1 product, the LLC-MK2 cells toxicity was observed until to the dilution 10^{-2}.

b) Cells sensitivity to the virus

The viruses were titrated on cell cultures untreated with the product (indicator cell line) and titrated on cell cultures treated with the product. According to the European standard EN 14476+A2, the F010474V1 product does not have an effect on the viruses titration method (the difference between viral titers must be < 1,0 log):

		Viral titer (log $TCID_{50}$)		
Dilution		Untreated cell cultures	Treated cell cultures	**Difference**
F010474V1	10^{-3}	7,75	7,50	**0,25**

c) VALIDATIONS OF THE COLD SHOCK METHOD

Concentration	**Organic soil load**	**Viral titer (log $TCID_{50}$)**	**Difference with the viral suspension**
F010474V1 80%	0,3 g/l BSA	TRIAL 1: 7,75	0,000
		TRIAL 2: 7,75	0,000

The method is validated if the difference is ≤ 0,5 log.

d) INACTIVATION ASSAYS OF THE VIRUS WITH A CONTROL SOLUTION

The viral titer reduction (difference between the titers of the viral suspension treated with 0,7 % formaldehyde and the viral suspension control) must be between:

- -0.5 and -2,5 log after 30 min

Formaldehyde 0,7%	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction (log $TCID_{50}$)**
Viral suspension control	7,75	
Inactivation 5 min	6,50	1,25
Inactivation 15 min	6,00	1,75
Inactivation 30 min	5,50	**2,25**

5 VIRUCIDAL ASSAYS

The concentrations of the product demonstrated a virucidal activity on the virus tested if the viral titer reduction is ≥ 4,0 log.

TRIAL 1 – The viral suspension was titrated at 7,75 log $TCID_{50}$.

PRODUCT	**Concentration (v/v)**	**Time of exposure**	**Temperature**	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction**
F010474V1	80%	5 min	20°C	4,50	3,25
		10 min		3,50	**4,25**
		60 min		2,50	**5,25**

TRIAL 2 - The viral suspension was titrated at 7,75 log $DICT_{50}$.

PRODUCT	Concentration (v/v)	Time of exposure	Temperature	Viral titer (log $TCID_{50}$)	Viral titer reduction
F010474V1	80%	5 min	20°C	4,00	3,75
		10 min		3,25	**4,50**
		60 min		2,75	**5,00**

6 VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 14476+A2:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product:
  - 7,750 log $TCID_{50}$ for poliovirus
- The virus was inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure:
  - the reduction observed was of 2,25 log for the poliovirus.
- The F010474V1 product does not have a cytotoxic effect on the LLC-MK2 cells.
- The F010474V1 product does not affect the infectious capacity of the viruses:
  - For poliovirus, the differences in viral titers between the virus inoculated on LLC-MK2 cells and the virus inoculated on the LLC-MK2 cells treated with the product was ≤ 1,0 log (0,250 log).

7 CONCLUSION

The assays performed with the F010474V1 product:

- **Demonstrated a virucidal activity on the poliovirus from the concentration 80%,** as required by the European standard EN 14476+A2, following a **10 min** exposure period, at 20°C, in clean conditions.

8 TECHNICAL APPENDIX 1

Cell line: LLC-MK2 cells (ATCC réf. CCL7, lot n°48677)

Viral strain: poliovirus type 1, strain LSc-2ab (ATCC réf. VR-59, lot n°659893)

Buffer and reagents:

- Buffer PBS: sodium chloride, Panreac, réf. 141659.1211, lot n° 0000204679; sodium phosphate dibasic, Sigma Aldrich, ref. S5136, batch n° BCBC7067V; sodium phosphate monobasic, Sigma Aldrich, ref. S5011, batch n° 1019K01021V
- MEM media, Sigma Aldrich, réf. 0268, lot n° 040M8301
- DMEM media, Sigma Aldrich, réf. D5796, lot n° RNBB9336
- Calf serum, Sigma Aldrich, ref. F7524, lot n° 098K3397

Organic soil load:

- Bovine Sera Albumin, Sigma Aldrich, réf. 05479, lot n° STBB7838V
- Sheep erythrocytes, Oxoïd, réf. SR 0051E, lot n° 4234000

Inactivation solution: Formaldehyde, Sigma Aldrich, ref. F-1635, batch n° BCBB3510

9 TECHNICAL APPENDIX 2

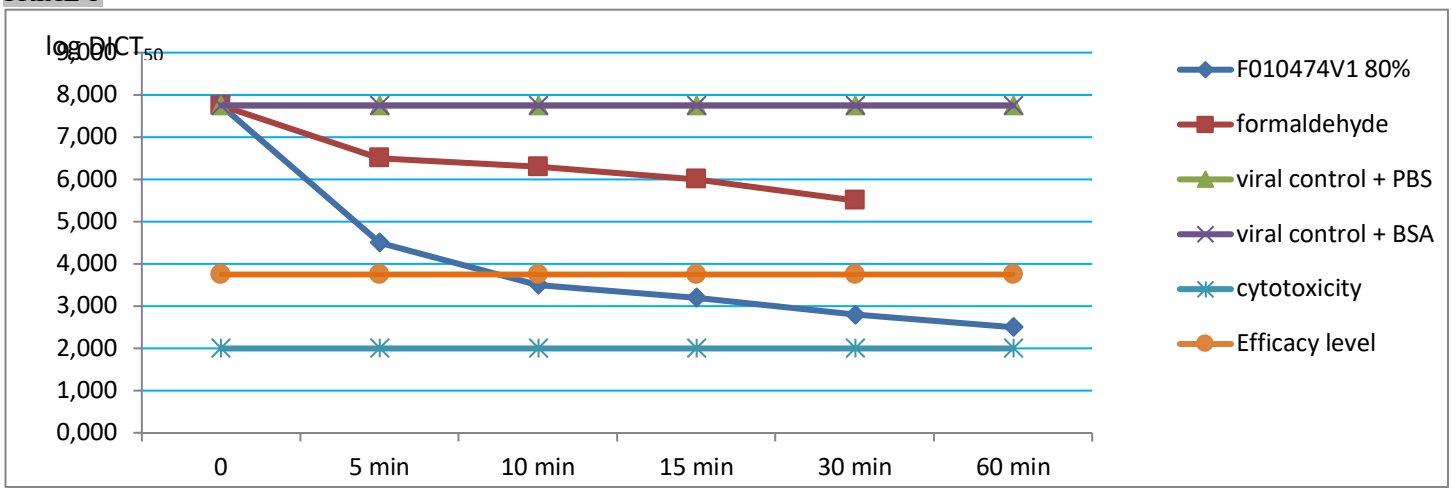
Table A1 – Poliovirus titer by Spaerman-Kärber method:

log $DICT_{50}$ = 7,75

Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	44444444	100
-7	11112111	100
-8	11000000	25
-9	00000000	0
-10	00000000	0
Sum of the % of positives cultures		525

Chart 1 – Trials on Poliovirus:

TRIAL 1



TRIAL 2

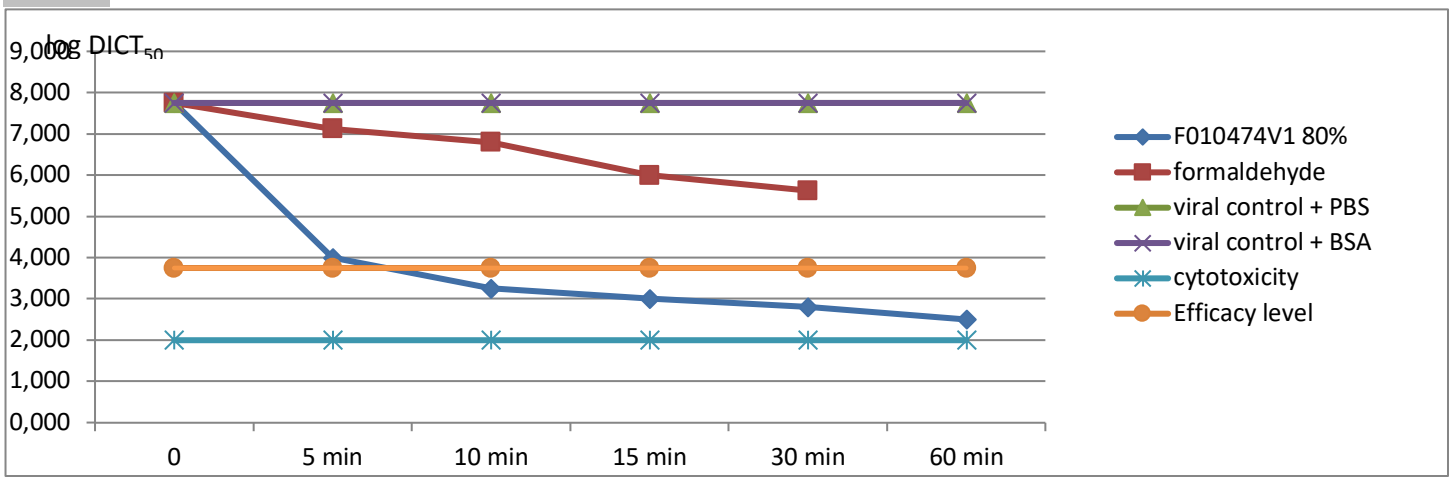


Table A2 — Results on poliovirus in clean conditions

PRODUCT	CONCENTRATION	ORGANIC SOIL LOAD	CYTOTOXICITY LEVEL	Lg $DICT_{50}$						Réduction
				0	5 min	10 min	15 min	30 min	60 min	
F010474V1 TRIAL 1	80,00%	0,3 g/l BSA	2	7,75	4,5	3,5	N.T.	N.T.	2,5	10 min R = 4,25
F010474V1 TRIAL 2	80,00%	0,3 g/l BSA	1,875	7,75	4	3,25	N.T.	N.T.	2,5	10 min R = 4,5
Formaldehyde trial 1	0,70%	PBS	2,5	7,75	6,5	N.T.	6	5,5	N.T.	
Formaldehyde trial 2	0,70%	PBS	2,5	7,75	7,125	N.T.	6	5,625	N.T.	
VIRAL CONTROL OF INFECTIVITY Trial 1	N.A.	PBS	N.A.	7,75	N.T.	N.T.	N.T.	N.T.	7,75	
VIRAL CONTROL OF INFECTIVITY Trial 1	N.A.	0,3 g/l BSA	N.A	7,75	N.T.	N.T.	N.T.	N.T.	7,75	
VIRAL CONTROL OF INFECTIVITY Trial 2	N.A.	PBS	N.A	7,75	N.T.	N.T.	N.T.	N.T.	7,75	
VIRAL CONTROL OF INFECTIVITY Trial 2	N.A.	0,3 g/l BSA	N.A	7,75	N.T.	N.T.	N.T.	N.T.	7,625	
CELL SENSITIVITY TO THE VIRUS	10^{-2}	N.A.	UNTREATED CELLS	7,75						
		N.A.	TREATED CELLS	7,5						

Table A3 — Raw results for trial 1

TRIAL 1

	Concentration	Organic soil load	Contact time	Dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1 TRIAL 1	80,00%	0,3 g/l BSA	5 min	4444	4444	1111	1111	0000	0000	0000	0000
				4444	4444	1111	1111	0000	0000	0000	0000
			10 min	4444	4444	1111	0000	0000	0000	0000	0000
				4444	4444	1111	0000	0000	0000	0000	0000
			60 min	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			VIRAL CONTROL	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
F010474V1 TRIAL 1 cytotoxicity	80,00%	0,3 g/l BSA	N.A.	4444	1111	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000
Formaldehyde	0,70%	PBS	5	4444	4444	4444	4444	4444	1111	0000	0000
				4444	4444	4444	4444	4444	1111	0000	0000
			15	4444	4444	4444	4444	4444	1111	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000
			30	4444	4444	4444	4444	1111	0000	0000	0000
				4444	4444	4444	4444	1111	0000	0000	0000
Formaldehyde (cytotoxicity)	0,70%	PBS	N.A.	4444	1111	0000	0000	N.T.	N.T.	N.T.	N.T.
				4444	1111	0000	0000				
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
			60	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	0,3 g/l BSA	0	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
			60	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000

TRIAL 2

	Concentration	Organic soil load	Contact time	Dilutions							
				-1	-2	-3	-4	-5	-6	-7	-8
F010474V1 TRIAL 2	80,00%	0,3 g/l BSA	5 min	4444	4444	1111	1111	0000	0000	0000	0000
				4444	4444	1111	0000	0000	0000	0000	0000
			10 min	4444	4444	1111	0000	0000	0000	0000	0000
				4444	4444	1100	0000	0000	0000	0000	0000
			60 min	4444	4444	4400	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000
			VIRAL CONTROL	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
F010474V1 TRIAL 2 cytotoxicity	80,00%	0,3 g/l BSA	N.A.	4444	1110	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000
Formaldehyde	0,70%	PBS	5	4444	4444	4444	4444	4444	1111	0000	0000
				4444	4444	4444	4444	4444	1111	0000	0000
			15	4444	4444	4444	4444	4444	1111	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000
			30	4444	4444	4444	4444	1111	1000	0000	0000
				4444	4444	4444	4444	1111	0000	0000	0000
Formaldehyde (cytotoxicity)	0,70%	PBS	N.A.	4444	1111	0000	0000	N.T.	N.T.	N.T.	N.T.
				4444	1111	0000	0000				
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
			60	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	4444	1111	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	0,3 g/l BSA	0	4444	4444	4444	4444	4444	4444	1111	1100
				4444	4444	3334	4444	4444	4444	1111	0000
			60	4444	4444	4444	4444	4444	4444	1111	1000
				4444	4444	4444	4444	4444	4444	1111	0000

Cells sensitivity to the virus :

Product	Dilution	Organic soil load		Dilutions						
				-2	-3	-4	-5	-6	-7	-8
F010474V1	10^{-3}	0,3 g/l BSA	Untreated cells	4444	4444	4444	4444	4444	1111	1100
				4444	4444	4444	4444	4444	1111	0000
			Treated cells	4444	4444	4444	4 444	4444	1111	0000
				4444	4444	4444	4444	4444	1111	0000

TEST REPORT

VIRUCIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 17111 :2018 STANDARD

Delivered to Ms CHAKCHOUK

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

Date of request: 06/14/2022

Study references: #155D61-2022-05

VIRUCIDAL TESTS:

According to the NF EN 17111 standard (October 2018) – chemical antiseptics and disinfectants – virucidal quantitative carrier tests for chemical disinfectants and antiseptics used in medical area (phase 2, step 2).

Tests using the F010474V1 product against *adenovirus* and *norovirus*.

This test report included 15 pages.

Study completion date: 10/07/2022

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

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

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
3, RUE DE LA TERRE ROUGE
Espace industriel de Beaupré
25 220 ROCHE LEZ BEAUPRE
FRANCE

2 PRODUCT IDENTITY

SAMPLE	BATCH N°
F010474V1	7729

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: peracetic acid

Appearance of the product: clear.

Product diluent recommended by the manufacturer for use: none, ready-to-use product.

Date of delivery of the product: 06/29/2022

Date of tests: 06/29/2022 to 07/29/2022

3 EXPERIMENTAL CONDITIONS

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

Titration unit: log $TCID_{50}$

Exposure time: 5 min and 10 min

Tested concentrations (final concentrations): 100% - 80%

Diluent used for the product: sterile hard water

Viral strains: adenovirus type 5, adenoid strain 75, grown on HEp-2 cells- murine norovirus, strain S99, grown on RAW 264.7 cells, at 37°C, under 5% CO2 atmosphere

Organic soil load: BSA 0,3 g/L (clean conditions)

Product stability: stable

Stop solution: cold shock

4 VIRAL TITRE

Viral titer of the virus, expressed in $TCID_{50}$, according to the Spearman-Kärber method:

- For adenovirus= 7,125 log $DICT_{50}$
- For norovirus= 7,000 log $DICT_{50}$

Writer	Supervisor
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5 VALIDATION

a) CYTOTOXICITY

For adenovirus, the cell toxicity was observed until to the dilution 10^{-1}.

For norovirus, the cell toxicity was observed until to the dilution 10^{-1}.

b) CELLS SENSITIVITY TO THE VIRUS

The viruses were titrated on cell cultures untreated with the product (indicator cell line) and titrated on cell cultures treated with the product. According to the European standard EN 17111, the F010474V1 product used at the dilution of 10^{-2} does not have an effect on the viruses titration method (the difference between viral titers must be < 1,0 log):

ADENOVIRUS	**Viral titer (log $TCID_{50}$)**		
PRODUCT DILUTION	Untreated cell cultures	Treated cell cultures	**Viral titer (log $TCID_{50}$)**
F010474V1 10^{-2}	7,125	6,375	**0,750**

NOROVIRUS	**Viral titer (log $TCID_{50}$)**		
PRODUCT DILUTION	Untreated cell cultures	Treated cell cultures	**Viral titer (log $TCID_{50}$)**
F010474V1 10^{-2}	7,000	6,375	**0,625**

c) VALIDATIONS OF THE COLD SHOCK METHOD

The method is validated if the difference is $\leq 0,5$ log.

FOR ADENOVIRUS

Product Concentration	**Organic soil load**	**Viral titer (log $TCID_{50}$)**	**Difference with the viral suspension**
F010474V1 100%	0,3 g/L BSA	trial 1: 7,125	0,000
		trial 2: 7,125	0,000

FOR NOROVIRUS

Product Concentration	**Organic soil load**	**Viral titer (log $TCID_{50}$)**	**Difference with the viral suspension**
F010474V1 100%	0,3 g/L BSA	trial 1: 7,000	0,000
		trial 2: 7,000	0,000

d) INACTIVATION ASSAYS OF THE VIRUS WITH A CONTROL SOLUTION

ADENOVIRUS	**Viral titer (log $TCID_{50}$)**	**Viral titer reduction (log $TCID_{50}$)**
Water control – viral suspension	5,875	
Glutardialdehyde 200 ppm		
Inactivation 5 min	1,625	**4,250**

The viral titer reduction (difference between the titers of the viral suspension treated with glutardialdehyde and the viral suspension control) must be ≥ 4 log after 5 min of exposure. The reduction is of 4,250 log, filling the criteria.

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NOROVIRUS	Viral titer (log $TCID_{50}$)	Viral titer reduction (log $TCID_{50}$)
Water control – viral suspension	5,500	
Glutardialdehyde 200 ppm		
Inactivation 5 min	1,250	**4,250**

The viral titer reduction (difference between the titers of the viral suspension treated with glutardialdehyde and the viral suspension control) must be ≥ 4 log after 5 min of exposure. The reduction is of 4,250 log, filling the criteria.

6 VIRUCIDAL ASSAYS

FOR ADENOVIRUS

Trial 1 – drying time 48 min

The viral suspension of the water control was titrated at **5,875 log $DICT_{50}$**

PRODUCT	Concentration	Time of exposure	Temperature	Viral titer (log $TCID_{50}$)	Viral titer reduction
F010474V1	100%	10 min	20°C	1,375	**4,500**
		5 min		1,750	**4,125**
	80%	10 min		2,125	3,750
		5 min		3,000	2.875

Trial 2– drying time 52 min

The viral suspension of the water control was titrated at **6,125 log $DICT_{50}$**

PRODUCT	Concentration	Time of exposure	Temperature	Viral titer (log $TCID_{50}$)	Viral titer reduction
F010474V1	100%	10 min	20°C	1,500	**4,625**
		5 min		1,875	**4,250**
	80%	10 min		2,500	3,625
		5 min		3,125	3,000

The concentrations of the product demonstrated a virucidal activity on the virus tested if the viral titer reduction is ≥ 4,0 log.

FOR NOROVIRUS

Trial 1 – drying time 51 min

The viral suspension of the water control was titrated at **5,500 log $DICT_{50}$**

PRODUCT	Concentration	Time of exposure	Temperature	Viral titer (log $TCID_{50}$)	Viral titer reduction
F010474V1	100%	10 min	20°C	1,125	**4,375**
		5 min		1,500	**4,000**
	80%	10 min		2,000	3,500
		5 min		2,750	2,750

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Trial 2– drying time 49 min

The viral suspension of the water control was titrated at **5,750 log DICT$_{50}$**

PRODUCT	Concentration	Time of exposure	Temperature	**Viral titer (log TCID$_{50}$)**	**Viral titer reduction**
F010474V1	100%	10 min	20°C	1,250	**4,500**
		5 min		1,500	**4,250**
	80%	10 min		2,500	3,250
		5 min		2,875	2,875

The concentrations of the product demonstrated a virucidal activity on the virus tested if the viral titer reduction is ≥ 4,0 log.

7 VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 1711:2018:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product:
  - 7,125 log TCID $_{50}$ for adenovirus
  - 7,000 log TCID $_{50}$ for norovirus
- The virus was inactivated with the control solution of glutardialdehyde after 5 min of exposure should be ≥ 4 log: the reduction observed was of 4,250 log for the adenovirus, and 4,250 log for the norovirus.
- The product does not have a cytotoxic effect on the cells.
- The experimental conditions with 0,3 g/L BSA do not interfere with the infectivity of the viruses.
- The product does not affect the infectious capacity of the viruses:
  - for adenovirus, the differences in viral titers between the virus inoculated on the cells and the virus inoculated on the cells treated with the product was ≤ 1,0 log (0,750 log)
  - for norovirus, the differences in viral titers between the virus inoculated on the cells and the virus inoculated on the cells treated with the product was ≤ 1,0 log (0,625 log)

8 CONCLUSION

The assays performed with the F010474V1 product:

- **Demonstrated a virucidal activity against the adenovirus and norovirus from the concentration 100%,** as required by the European standard EN 17111:2018, following a **5 min exposure period, at 20°C, in clean conditions.**

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9 TECHNICAL APPENDIX 1

Adenovirus:

Cell line: HEp- 2 cells (RD-Biotech ref. 84011, batch n°110315-118)

Viral strain: adenovirus type 5, adenoïd strain 75 (ATCC ref. VR-5, batch n°3679877)

Norovirus:

Cell line: RAW 264.7 cells (ATCC TIB-71)

Viral strain: Murine norovirus, STRAIN S99 (batch n° 4/200409/220409- Friedrich Loeffler Institut)

Buffer and reagents:

- Buffer PBS: sodium chloride, Dominique DUTSCHER, ref. 836751; sodium phosphate dibasic, Sigma Aldrich, ref. S5136, batch n° BCBC7067V; sodium phosphate monobasic, Sigma Aldrich, ref. S5011, batch n° 1019K01021V
- MEM media, Sigma Aldrich, ref. 0268, batch n° 040M8301
- DMEM media, Sigma Aldrich, ref. D5796, batch n° RNBB9336
- Fetal calf serum, Sigma Aldrich, ref. F7524, batch n° 098K3397

Organic soil load:

- Bovine Sera Albumin, Sigma Aldrich, ref. 05479, bath n° STBB7838V
- Sheep erythrocytes, OXOID, ref. SR 0051E, batch 4234000

Inactivation solution: glutardialdehyde, Sigma Aldrich, ref. F-1635, batch n° BCBB3510

GLASS CARRIERS – frosted glass 15 x 60 mm, 1 mm thick – Thermo scientific/ Menzel-Gläser – ref. 100 OTM, batch n°01 1794389

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10 TECHNICAL APPENDIX 2

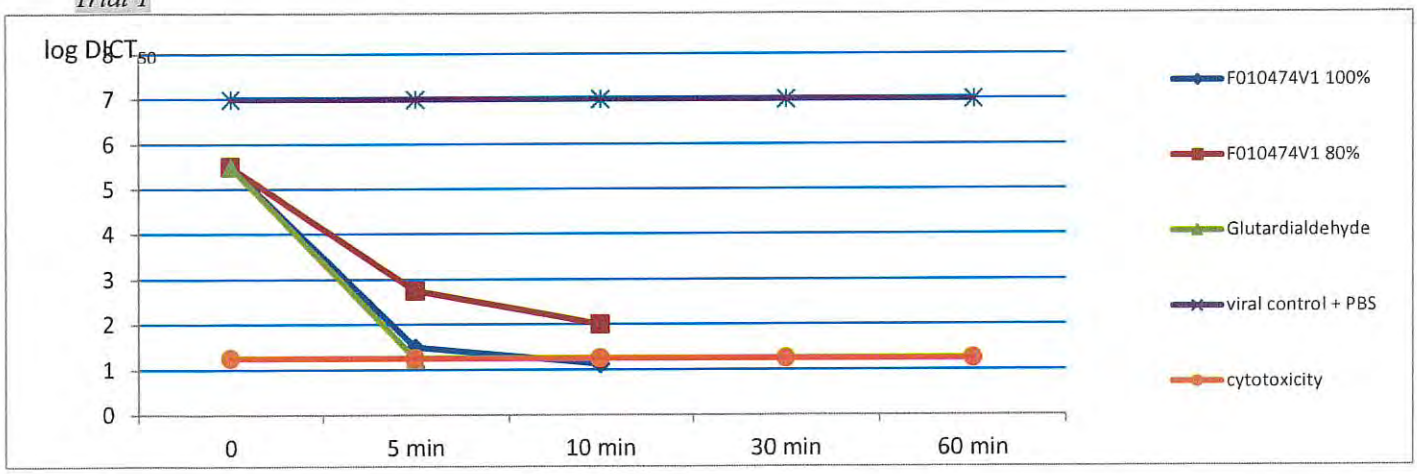
Table A1 – adenovirus titer, by Spaerman-Kärber method:

Log $DICT_{50}$ = 7,125

Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	44444444	100
-7	44444000	62,5
-8	00000000	0
-9	00000000	0
-10	00000000	0
Sum of % of positive results		462,5

Chart of the results

Trial 1



Trial 2

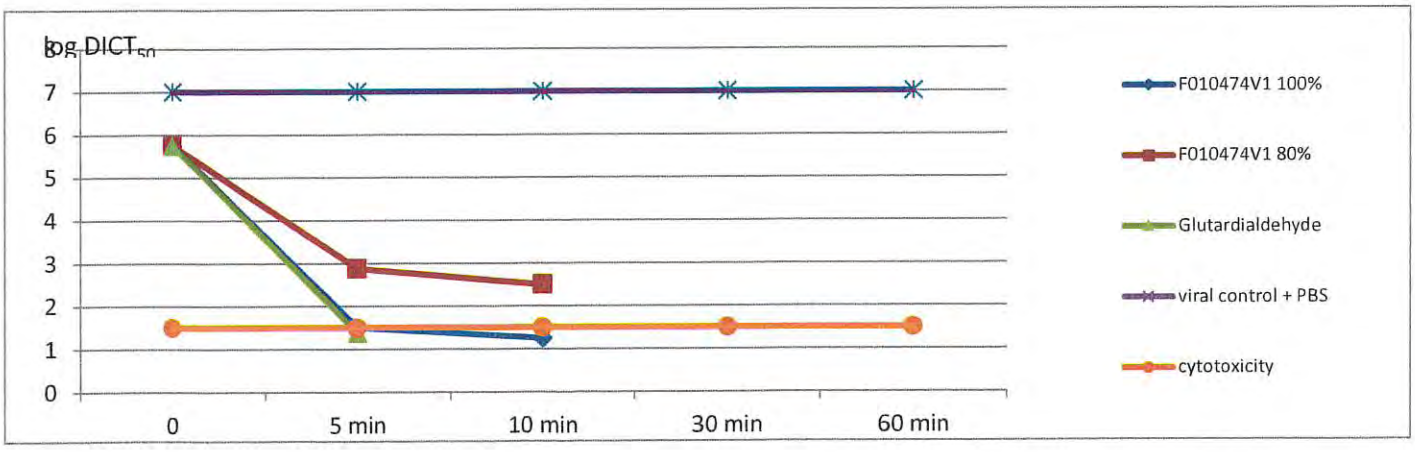


Table A2 — Results of F010474V1 product on adenovirus in clean conditions

PRODUCT	Concentration	ORGANIC SOIL LOAD	CYTOTOXICITY LEVEL	Lg $TCID_{50}$					Reduction
				0	5 min	10 min	30 min	60 min	
F010474V1 TRIAL 1	100,00%	0,3 g/L BSA	1,500	5,875	1,750	1,375	N.T.	N.T.	5 min R = 4,125
F010474V1 TRIAL 1	80,00%	0,3 g/L BSA	N.T.	5,875	3,000	2,125	N.T.	N.T.	10 min R = 3,750
F010474V1 TRIAL 2	100,00%	0,3 g/L BSA	1,500	6,125	1,875	1,500	N.T.	N.T.	5 min R = 4,250
F010474V1 TRIAL 2	80,00%	0,3 g/L BSA	N.T.	6,125	3,125	2,500	N.T.	N.T.	10 min R = 3,625
Glutardialdehyde TRIAL 1	100 ppm	PBS	1,875	5,875	1,625	N.T.	N.T.	N.T.	
Glutardialdehyde TRIAL 2	100 ppm	PBS	2,000	6,125	1,625	N.T.	N.T.	N.T.	
VIRAL CONTROL OF INFECTIVITY TRIAL 1	N.A.	PBS	N.A.	7,125	N.T.	N.T.	N.T.	7,125	
VIRAL CONTROL OF INFECTIVITY TRIAL 1	N.A.	0,3 g/L BSA	N.A	7,125	N.T.	N.T.	N.T.	7,125	
VIRAL CONTROL OF INFECTIVITY TRIAL 2	N.A.	PBS	N.A	7,125	N.T.	N.T.	N.T.	7,125	
VIRAL CONTROL OF INFECTIVITY TRIAL 2	N.A.	0,3 g/L BSA	N.A	7,125	N.T.	N.T.	N.T.	7,125	
CELL SENSITIVITY OF THE VIRUS	10^{-2}	N.A.	Untreated cells	7,125					
		N.A.	Treated cells	6,375					

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Table A3 — Raw results Trial 1

	Concentration	ORGANIC SOIL LOAD	EXPOSURE TIME	Dilutions								
				-1	-2	-3	-4	-5	-6	-7	-8	-9
F010474V1 TRIAL 1	100,00%	0,3 g/L BSA	10 min	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4440	0000	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	4400	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
	80,00%		10 min	4444	4444	0000	0000	0000	0000	0000	0000	0000
				4444	4000	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000
			WATER CONTROL	4444	4444	4444	4444	4444	4440	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
F010474V1 cytotoxicity	100,00%	0,3 g/L BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde	100 ppm	PBS	5	4444	4000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde (cytotoxicity)	100 ppm	PBS	N.A.	4444	0000	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	0000	0000	0000					
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	0,3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000

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Table A4 — Raw results Trial 2

	Concentration	ORGANIC SOIL LOAD	EXPOSURE TIME	Dilutions								
				-1	-2	-3	-4	-5	-6	-7	-8	-9
F010474V1 TRIAL 2	100%	0,3 g/L BSA	10 min	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	4440	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
	80%		10 min	4444	4444	0000	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	4000	0000	0000	0000	0000	0000	0000
			WATER CONTROL	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4000	0000	0000	0000
F010474V1 cytotoxicity	100%	0,3 g/L BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde	100 ppm	PBS	5	4444	4000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde (cytotoxicity)	100 ppm	PBS	N.A.	4444	0000	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	0000	0000	0000					
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	0,3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	4000	0000	0000

Table A5 – Cell sensitivity to the virus:

Product	Dilution	Organic soil load		Dilutions							
				-2	-3	-4	-5	-6	-7	-8	-9
F010474V1	10^{-2}	0,3 g/l BSA	Untreated cells	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4000	0000	0000
			Treated cells	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4440	0000	0000	0000

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11 TECHNICAL APPENDIX 2

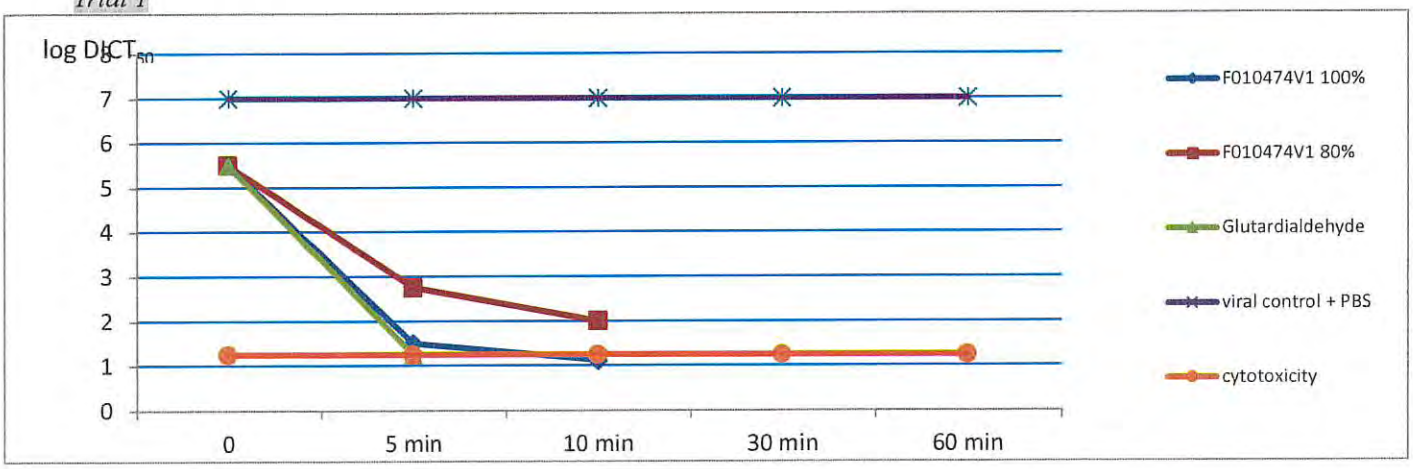
Table A6 – norovirus titer, by Spaerman-Kärber method:

Log $DICT_{50}$ = 7,000

Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	44444444	100
-7	44440000	50
-8	00000000	0
-9	00000000	0
-10	00000000	0
Sum of % of positive results		450,0

Chart of the results

Trial 1



Trial 2

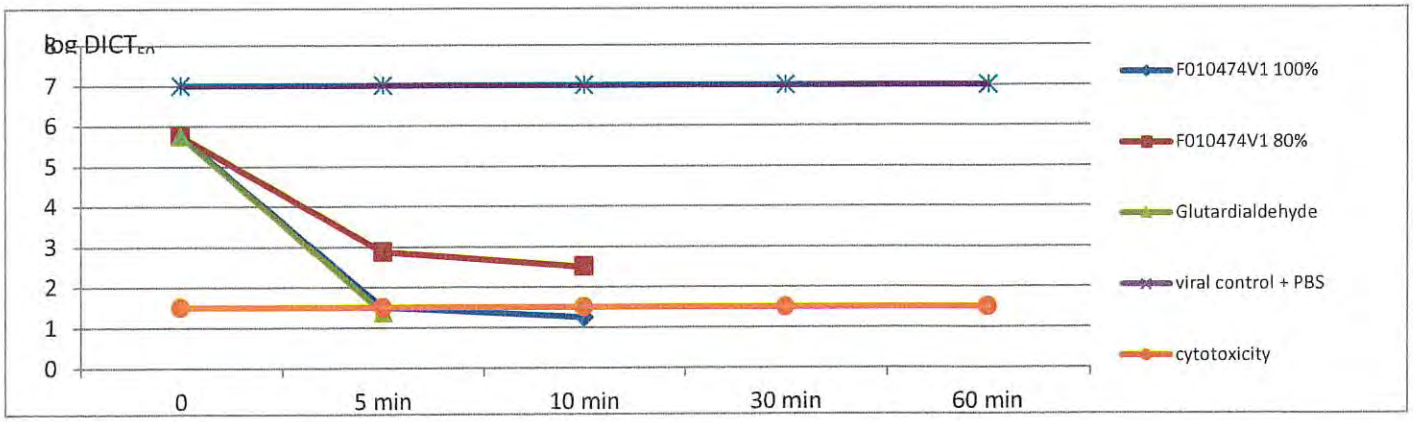


Table A7 — Results of F010474V1 product on norovirus in clean conditions

PRODUCT	Concentration	ORGANIC SOIL LOAD	CYTOTOXICITY LEVEL	Lg $TCID_{50}$					Reduction
				0	5 min	10 min	30 min	60 min	
F010474V1 TRIAL 1	100,00%	0,3 g/L BSA	1,250	5,500	1,500	1,125	N.T.	N.T.	5 min R = 4,000
F010474V1 TRIAL 1	80,00%	0,3 g/L BSA	N.T.	5,500	2,750	2,000	N.T.	N.T.	10 min R = 3,500
F010474V1 TRIAL 2	100,00%	0,3 g/L BSA	1,500	5,750	1,500	1,250	N.T.	N.T.	5 min R = 4,250
F010474V1 TRIAL 2	80,00%	0,3 g/L BSA	N.T.	5,750	2,875	2,500	N.T.	N.T.	10 min R = 3,250
Glutardialdehyde TRIAL 1	100 ppm	PBS	1,875	5,500	1,250	N.T.	N.T.	N.T.	
Glutardialdehyde TRIAL 2	100 ppm	PBS	2,000	5,750	1,375	N.T.	N.T.	N.T.	
VIRAL CONTROL OF INFECTIVITY TRIAL 1	N.A.	PBS	N.A.	7,000	N.T.	N.T.	N.T.	7,000	
VIRAL CONTROL OF INFECTIVITY TRIAL 1	N.A.	0,3 g/L BSA	N.A	7,000	N.T.	N.T.	N.T.	7,000	
VIRAL CONTROL OF INFECTIVITY TRIAL 2	N.A.	PBS	N.A	7,000	N.T.	N.T.	N.T.	7,000	
VIRAL CONTROL OF INFECTIVITY TRIAL 2	N.A.	0,3 g/L BSA	N.A	7,000	N.T.	N.T.	N.T.	7,000	
CELL SENSITIVITY OF THE VIRUS	10^{-2}	N.A.	Untreated cells	7,000					
		N.A.	Treated cells	6,375					

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Table A8 — Raw results Trial 1

	Concentration	ORGANIC SOIL LOAD	EXPOSURE TIME	Dilutions								
				-1	-2	-3	-4	-5	-6	-7	-8	-9
F010474V1 TRIAL 1	100,00%	0,3 g/L BSA	10 min	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4000	0000	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
	80,00%		10 min	4444	4444	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	4444	4400	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000
			WATER CONTROL	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
F010474V1 cytotoxicity	100,00%	0,3 g/L BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4400	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde	100 ppm	PBS	5	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4400	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde (cytotoxicity)	100 ppm	PBS	N.A.	4444	0000	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	0000	0000	0000					
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	0,3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000

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Table A9 — Raw results Trial 2

	Concentration	ORGANIC SOIL LOAD	EXPOSURE TIME	Dilutions								
				-1	-2	-3	-4	-5	-6	-7	-8	-9
F010474V1 TRIAL 2	100,00%	0,3 g/L BSA	10 min	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4400	0000	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
	80,00%		10 min	4444	4444	0000	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000
			5 min	4444	4444	4440	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000
			WATER CONTROL	4444	4444	4444	4444	4444	4400	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
F010474V1 cytotoxicity	100,00%	0,3 g/L BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde	100 ppm	PBS	5	4444	0000	0000	0000	0000	0000	0000	0000	0000
				4440	0000	0000	0000	0000	0000	0000	0000	0000
Glutardialdehyde (cytotoxicity)	100 ppm	PBS	N.A.	4444	0000	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.
				4000	0000	0000	0000					
VIRAL CONTROL OF INFECTIVITY	N.A.	PBS	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000
VIRAL CONTROL OF INFECTIVITY	N.A.	0,3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000
			60	4444	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000

Table A10 – Cell sensitivity to the virus:

Product	Dilution	Organic soil load		Dilutions							
				-2	-3	-4	-5	-6	-7	-8	-9
F010474V1	10^{-2}	0,3 g/l BSA	Untreated cells	4444	4444	4444	4444	4444	4444	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000
			Treated cells	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4440	0000	0000	0000

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

Sponsor : FRANKLAB

TEST REPORT

TUBERCULOCIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 14348 STANDARD

Delivered to **Ms CHAKCHOUK**

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

Date of request: 08/01/2014

Study number: n°295D11-2014-03

MYCOBACTERICIDAL TESTS:

According to the European standard NF EN 14348 (June 2005) – Chemical disinfectants and antiseptics - Test suspension for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area -
Test method and requirements (phase 2, step 2)

Tests using the F010474V1 product against 2 reference strains: *Mycobacterium terrae* and *Mycobacterium avium*.

This test report included 13 pages.

Study completion date: 02/19/2015

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

Product	Batch N°
F010474V1	4494

Expiration date: non communicated

Manufacturer : FRANKLAB

Manufacturing date: non communicated

Storage conditions: room temperature

Active substances : peracetic acid

Appearance of the product: liquid, colorless

Product diluent recommended by the manufacturer for use: none, ready-to-use product

Date of delivery of the product: 11/26/2014

Date of tests: from 12/02/2014 to 01/29/2015

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 80%

Appearance of the product and its dilutions: clear.

Method: dilution-neutralization.

Exposure time: 5 min, 10 min, 15 min and 60 min

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

Diluent used for the assays: distilled water.

Diluent used for the mycobacterial suspensions: sterile trypton salt solution.

Organic soil load: clean conditions, Bovine Serum Albumin (BSA) 0,3 g/L

Product stability: limpid solution with organic soil load

Neutralizer: sodium thiosulfate

Strains*:* *Mycobacterium avium* CIP 105415, batch n° 23606 and *Mycobacterium terrae* CIP 104321, batch n°16308 (Institut Pasteur).

Media: Middlebrook 7H9 ADC 10% broth, Middlebrook 7H10 OADC 10% media, 37°C ± 1°C.

4 VALIDATIONS AND ASSAYS

See results sheets.

The tuberculocidal activity is demonstrated if the reduction of the population is ≥ 4 log.

- *Mycobacterium terrae*, R = 5,03 (10 min)
- *Mycobacterium avium*, R = 5,05 (10 min)

5 CONCLUSION

According to the EN 14348 standard (June 2005), the F1031V2 product:

- demonstrated a tuberculocidal activity against *Mycobacterium terrae* strain in 10 min at 20°C, under clean conditions, when used pure

- demonstrated a mycobactericidal activity against *Mycobacterium terrae* and *Mycobacterium avium* strains in 10 min at 20°C, under clean conditions, when used pure

6 SHEETS OF RESULTS

See below.

Methodology controls:
- 1,5 x 10^9 UFC/ml≤ N ≤ 5,0 x 10^9 UFC/ml
- 3 x 10^2 UFC/ml≤ Nv 1,6 x 10^3
- 30≤ Nv0 ≤160 UFC/ml
- A, B and C ≥0,5 x Nv0

Vc = number of colonies on Petri dish
Nv 0= number of colonies / ml in A, B and C solutions
N = number of CFU/ml of the test suspension
Na = number of survivor per ml after time exposure with the product
A = number of CFU/ml in validation assay of experimental conditions
B = number of CFU/ml in validation assay of non-toxicity of the Neutralizer
C = number of CFU/ml in validation assay of the dilution-neutralization method
$\bar{x}$ = average of Vc1 and Vc2
LOG R = reduction (lg R = lg N0 – lg Na)

7 *Mycobacterium terrae* - trial

Standard: EN 14348 Product : **F010474V1** Batch N° : 4494 Study N° : 295D11-2014-03 Date of trials : 01/06/2015	Method: ☒ Pour plating ☐ Spread plating ☒ Number of petri dishes: 2 petri dish / ml	Neutralizer : sodium thiosulfate 2% Temperature of trials : 20°C Organic soil load : 0,3 g/L BSA Incubation temperature : 37°C ± 1°C Diluent : sterile distilled water

VALIDATIONS

	Suspension of validation **Nv0**		VALIDATION **A**		VALIDATION **B**		VALIDATION **C**	
Vc1	58	$\bar{x}$	77	$\bar{x}$	65	$\bar{x}$	59	$\bar{x}$
Vc2	61	60	83	80	67	66	58	59
	30 ≤ $\bar{x}$ de Nv0 ≤160 x yes □ no		$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 x yes □ no	

TRIAL SUSPENSION AND TRIAL

Trial Suspension (N)			**log N**	**log N0**
10^{-7}	255	256	9,40	8,40
10^{-8}	25	23		
8,17 ≤ log N0 ≤ 8,70? x yes □ no				

Product	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\bar{x}$ x 10)	lg R = lg N0 – lg Na	Contact time
	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2			
80 %	>660	>660	263	262	26	28	2	4	4,42	3,98	5 min
	226	225	18	25	1	1	0	0	3,35	**5,05**	10 min
	156	159	17	15	0	0	1	0	3,20	**5,21**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>6,25**	60 min

8 *Mycobacterium terrae* - repetition

Standard: EN 14348 Product : **F010474V1** Batch N° : 4494 Study N° : 295D11-2014-03 Date of trials : 01/06/2015	Method: ☒ Pour plating ☐ Spread plating ☒ Number of petri dishes: 2 petri dish / ml	Neutralizer : sodium thiosulfate 2% Temperature of trials : 20°C Organic soil load : 0,3 g/L BSA Incubation temperature : 37°C ± 1°C Diluent : sterile distilled water

VALIDATIONS

	Suspension of validation **Nv0**		VALIDATION **A**		VALIDATION **B**		VALIDATION **C**	
Vc1	51	$\bar{x}$	77	$\bar{x}$	70	$\bar{x}$	59	$\bar{x}$
Vc2	45	48	81	79	61	66	57	58
	30 ≤ $\bar{x}$ de Nv0 ≤160 x yes □ no		$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 x yes □ no	

TRIAL SUSPENSION AND TRIAL

Trial Suspension (N)			**log N**	**log N0**
10^{-7}	221	230	9,37	8,37
10^{-8}	28	32		
8,17 ≤ log N0 ≤ 8,70? x yes □ no				

Product	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\bar{x}$ x 10)	lg R = lg N0 – lg Na	Contact time
	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2			
80 %	>660	>660	249	261	24	20	5	2	4,40	3,96	5 min
	231	225	23	20	1	2	0	0	3,36	**5,01**	10 min
	160	146	19	20	2	3	0	0	3,20	**5,17**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>6,22**	60 min

9 *Mycobacterium avium* - trial

Standard: EN 14348 Product : **F010474V1** Batch N° : 4494 Study N° : 295D11-2014-03 Date of trials : 01/06/2015	Method: ☒ Pour plating ☐ Spread plating ☒ Number of petri dishes: 2 petri dish / ml	Neutralizer : sodium thiosulfate 2% Temperature of trials : 20°C Organic soil load : 0,3 g/L BSA Incubation temperature : 37°C ± 1°C Diluent : sterile distilled water

VALIDATIONS

	Suspension of validation **Nv0**		VALIDATION **A**		VALIDATION **B**		VALIDATION **C**	
Vc1	68	$\bar{x}$	82	$\bar{x}$	67	$\bar{x}$	72	$\bar{x}$
Vc2	70	69,0	77	79,5	67	67,0	65	68,5
	30 ≤ $\bar{x}$ de Nv0 ≤160 x yes □ no		$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 x yes □ no	

TRIAL SUSPENSION AND TRIAL

Trial Suspension (N)			**log N**	**log N0**
10^{-7}	260	258	9,41	8,41
10^{-8}	26	21		
8,17 ≤ log N0 ≤ 8,70? x yes □ no				

Product	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\bar{x}$ x 10)	lg R = lg N0 – lg Na	CONTACT TIME
	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2			
80 %	>660	>660	283	284	20	24	1	1	4,44	3,97	5 min
	243	221	23	24	2	1	0	0	3,37	**5,04**	10 min
	173	157	19	20	1	4	0	0	3,22	**5,19**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>6,26**	60 min

10 *Mycobacterium avium* – repetition

Standard: EN 14348 Product : **F010474V1** Batch N° : 4494 Study N° : 295D11-2014-03 Date of trials : 01/06/2015	Method: ☒ Pour plating ☐ Spread plating ☒ Number of petri dishes: 2 petri dish / ml	Neutralizer : sodium thiosulfate 2% Temperature of trials : 20°C Organic soil load : 0,3 g/L BSA Incubation temperature : 37°C ± 1°C Diluent : sterile distilled water

VALIDATIONS

	Suspension of validation **Nv0**		VALIDATION **A**		VALIDATION **B**		VALIDATION **C**	
Vc1	57	$\bar{x}$	80	$\bar{x}$	75	$\bar{x}$	72	$\bar{x}$
Vc2	52	55	80	80	67	71	71	72
	30 ≤ $\bar{x}$ de Nv0 ≤160 x yes □ no		$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 x yes □ no		$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 x yes □ no	

TRIAL SUSPENSION AND TRIAL

Trial Suspension (N)			**log N**	**log N0**
10^{-7}	251	240	9,39	8,39
10^{-8}	25	25		
8,17 ≤ log N0 ≤ 8,70? x yes □ no				

Product	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\bar{x}$ x 10)	lg R = lg N0 – lg Na	CONTACT TIME
	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2	Vc1	Vc2			
80 %	>660	>660	260	279	22	23	2	2	4,42	**3,97**	5 min
	220	217	18	21	1	1	0	0	3,34	**5,06**	10 min
	156	157	17	17	1	0	0	0	3,20	**5,19**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>6,24**	60 min

11 TECHNICAL APPENDIX

MEDIA

- Middlebrook broth 7H9, FLUKA, ref. 100957898, batch n° BCBC4788
- ADC 10%, FLUKA, ref. 101007527, batch n° BCBD4192
- Middlebrook media and Cohn 7H10 SIGMA-ALDRICH, ref. M0303, batch n°1405662
- OADC 10%, FLUKA, ref. 100962567, batch n° BCBC5497

DILUENT

Trypton-Salt Solution _ Per liter of distilled water:

- Trypton, Dominique Dutscher, ref. 777472, batch n° 090633 1,00 g
- Sodium Chloride, Grosseron, ref. 9020401, batch n° FR08 085 793 8,50 g

Final pH at 25°C : 7,0 ± 0,2

NEUTRALIZER

Ingredients per liter of distilled water:

- Tween 80, Sigma Aldrich, ref 59924, batch BCBJ6978V 30 g
- Egg yolk 5 g

Sterilised by autoclaving

ORGANIC SOIL LOAD

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

TEST REPORT

TUBERCULOCIDAL AND MYCOBACTERICIDAL ACTIVITY ON F010474V1 PRODUCT ACCORDING TO THE EN 14563 STANDARD

Delivered to: Ms CHAKCHOUK

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

Date of request: 08/01/2014

Study references: n°295D11-2014-04

MYCOBACTERICIDAL TESTS ON CARRIERS:

According to the European standard NF EN 14563 (February 2009) – Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area -
Test method and requirements (phase 2, step 2)
Tests using the F010474V1 product against the strains *Mycobacterium terrae* and *Mycobacterium avium*.

This test report included 13 pages.

Study completion date: 02/19/2015

Stephanie MOROT - BIZOT
PhD in Microbiology
Study Director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

SAMPLE	BATCH N°
F010474V1	4494

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: peracetic acid

Appearance of the product: liquid, colorless.

Product diluent recommended by the manufacturer for use: none, ready-to-use product.

Date of delivery of the product: 11/26/2014

Date of tests: 12/02/2014 to 01/29/2015

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 100%

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 5 min - 10 min - 15 min – 60 min

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

Organic soil load: clean conditions, BSA 0,3 g/L

Diluent used for the assays: hard water

Strains: *Mycobacterium terrae* CIP 104321, batch n°16308 (Institut Pasteur) and *Mycobacterium avium* CIP 105415, batch n° 23606 (Institut Pasteur).
Media: Middlebrook 7H9 ADC 10% broth, Middlebrook 7H10 OADC 10% media, 37°C ± 1°C.

Product stability during the tests: good

Stop solution : sodium thiosulfate 2%

4 VALIDATIONS AND RESULTS SHEETS

Attached below.

– *Mycobacterium terrae*, **R = 4.10, for 10 min of exposure time**

– *Mycobacterium avium*, **R = 4.03, for 10 min of exposure time**

5 CONCLUSIONS

According to the EN 14563 standard (February 2009), the F010474V1 product:

- Demonstrated a tuberculocidal activity against *Mycobacterium terrae* strain for an exposure time of 10 min at 20°C, in clean conditions from the concentration of 100%.

- Demonstrated a mycobactericidal activity against *Mycobacterium terrae* and *Mycobacterium avium* strains for an exposure time of 10 min at 20°C, in clean conditions from the concentration of 100%.

6 RESULTS SHEETS

See below.

For all result sheets:

Methodology controls:
- $1,5 \times 10^9$ UFC/ml$\leq N \leq 5,0 \times 10^9$ UFC/ml
- $1,4 \times 10^6$ UFC/ml$\leq$ Nwt $\leq$ lg N-1,3
- $30 \leq$ Nv0 ≤ 160 UFC/ml
- A, B and C $\geq 0,5 \times$ Nv0

Legend:

Vc: value is the number of cfu/ml
$\bar{x}$: average (Vc1 and Vc2)
N : number of cfu/ml of the bacterial suspension
Nw: number of cfu/ml of the control bacterial test suspension
Na: number of survivors per ml in the test mixture at the end of the time exposure
Nv0: number of cfu/ml of the bacterial test suspension in the mixture A, B and C at the beginning of the time exposure
R = reduction (lg R = lg N0 – lg Na)

SHEET OF RESULTS 1 - *Mycobacterium terrae* (trial)

STANDARD: EN 14653, phase 2, step 2
PRODUCT : F010474V1
Batch: 4494
Number of petri dishes: 2 petri dish / mL

Neutralizer : sodium thiosulfate 2%

Temperature of trials: 20°C

Organic soil load: bovine serum albumin 0,3 g/L

Strain: *Mycobacterium terrae* CIP 104321

Date of trials: 01/06/2015

Technical manager: Stephanie MOROT-BIZOT

Signature :

Validations and controls

Suspension of validation Nv0			Experimental conditions control (A)			Control of neutralization (B)			Validation of dilution-neutralization method product concentration (C) 100% 15 min		
Vc1	58 (30+28)	$\bar{x}$ = 59,5	Vc1	66 (33+33)	$\bar{x}$ = 64	Vc1	53 (26+27)	$\bar{x}$ = 55,5	Vc1	55 (26+29)	$\bar{x}$ = 53,5
Vc2	61 (30+31)		Vc2	62 (30+32)		Vc2	58 (28+30)		Vc2	52 (24+28)	
30 ≤ $\bar{x}$ de Nv0 ≤160 ☒ yes no			$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 ☒ yes no		

Test suspension and test

TRIAL SUSPENSION N	**N**	**Vc1**	**Vc2**	N = 2,50 x 10^9 lg N = 9,41
	10^{-7}	255	256	9,17 ≤ lg N ≤ 9,70?
	10^{-8}	25	23	×yes no

WATER CONTROL Nw		**Vc1**	**Vc2**	Nw = $\bar{x}$ x 10 = 5,7x 10^6 lg Nw = 6,75
	10^{-4}	58	56	6,15 ≤ log Nw ≤ (log N-1,3)?
	10^{-5}	7	4	×yes no

	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\bar{x}$ x 10)	lg R = lg Nw – lg Na	CONTACT TIME
	Vc1	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**			
PRODUCT 100%	70	68	5	4	0	0	0	0	2,84	3,91	5 min
	52	42	0	0	0	0	0	0	2,67	**4,08**	10 min
	25	31	1	1	0	0	0	0	2,45	**4,30**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>4,60**	60 min

SHEET OF RESULTS 2 - *Mycobacterium terrae* (repetition)

STANDARD: EN 14653, phase 2, step 2
PRODUCT : F010474V1
Batch: 4494
Number of petri dishes: 2 petri dish / mL

Neutralizer : sodium thiosulfate 2%

Temperature of trials: 20°C

Organic soil load: bovine serum albumin 0,3 g/L

Strain: *Mycobacterium terrae* CIP 104321

Date of trials: 01/06/2015

Technical manager: Stephanie MOROT-BIZOT

Signature :

Validations and controls

Suspension of validation Nv0			Experimental conditions control (A)			Control of neutralization (B)			Validation of dilution-neutralization method product concentration (C) 100% 15 min		
Vc1	51 (28+23)	$\bar{x}$ = 48	Vc1	58 (30+28)	$\bar{x}$ = 56,5	Vc1	50 (26+24)	$\bar{x}$ = 49,5	Vc1	43 (21+22)	$\bar{x}$ = 45
Vc2	45 (20+25)		Vc2	55 (27+28)		Vc2	49 (25+24)		Vc2	47 (24+23)	
30 ≤ $\bar{x}$ de Nv0 ≤160 ☒ yes no			$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 ☒ yes no		

Test suspension and test

TRIAL SUSPENSION N	**N**	**Vc1**	**Vc2**	N = 2,30 x 10^9 lg N = 9,36 9,17 ≤ lg N ≤ 9,70? ×yes no
	10^{-7}	221	230	
	10^{-8}	28	32	

WATER CONTROL Nw		**Vc1**	**Vc2**	Nw = $\bar{x}$ x 10 = 5,1x 10^6 lg Nw = 6,71 6,15 ≤ log Nw ≤ (log N-1,3)? ×yes no
	10^{-4}	54	50	
	10^{-5}	3	5	

	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\overline{x}$ x 10)	lg R = lg Nw – lg Na	CONTACT TIME
	Vc1	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**			
PRODUCT 100%	81	67	2	7	0	0	0	0	2,87	3,84	5 min
	43	36	2	1	0	0	0	0	2,60	**4,11**	10 min
	20	27	3	2	0	0	0	0	2,37	**4,34**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>4,56**	60 min

SHEET OF RESULTS 3 - *Mycobacterium avium* (trial)

STANDARD: EN 14653, phase 2, step 2
PRODUCT : F010474V1
Batch: 4494
Number of petri dishes: 2 petri dish / mL

Neutralizer : sodium thiosulfate 2%

Temperature of trials: 20°C

Organic soil load: bovine serum albumin 0,3 g/L

Strain: *Mycobacterium avium* CIP 105415

Date of trials: 01/06/2015

Technical manager: Stephanie MOROT-BIZOT

Signature :

Validations and controls

Suspension of validation Nv0			Experimental conditions control (A)			Control of neutralization (B)			Validation of dilution-neutralization method product concentration (C) 100% 15 min		
Vc1	68 (33+35)	$\bar{x}$ = 69	Vc1	57 (28+29)	$\bar{x}$ = 56	Vc1	47 (25+22)	$\bar{x}$ = 49	Vc1	40 (21+19)	$\bar{x}$ = 41,5
Vc2	70 (35+35)		Vc2	55 (28+27)		Vc2	51 (24+27)		Vc2	43 (20+23)	
30 ≤ $\bar{x}$ de Nv0 ≤160 ☒ yes no			$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 ☒ yes no		

Test suspension and test

TRIAL SUSPENSION N	**N**	**Vc1**	**Vc2**	N = 2,60 x 10^9 lg N = 9,42 9,17 ≤ lg N ≤ 9,70? ×yes no
	10^{-7}	260	258	
	10^{-8}	26	21	

WATER CONTROL Nw		**Vc1**	**Vc2**	Nw = $\bar{x}$ x 10 = 4,5x 10^6 lg Nw = 6,66 6,15 ≤ log Nw ≤ (log N-1,3)? ×yes no
	10^{-4}	49	47	
	10^{-5}	4	0	

	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\overline{x}$ x 10)	lg R = lg Nw – lg Na	CONTACT TIME
	Vc1	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**			
PRODUCT 100%	60	61	3	7	0	0	0	0	2,78	3,88	5 min
	44	40	1	4	0	0	0	0	2,62	**4,04**	10 min
	36	27	1	1	0	0	0	0	2,50	**4,16**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>4,51**	60 min

SHEET OF RESULTS 4 - *Mycobacterium avium* (repetition)

STANDARD: EN 14653, phase 2, step 2
PRODUCT : F010474V1
Batch: 4494
Number of petri dishes: 2 petri dish / mL

Neutralizer : sodium thiosulfate 2%

Temperature of trials: 20°C

Organic soil load: bovine serum albumin 0,3 g/L

Strain: *Mycobacterium avium* CIP 105415

Date of trials: 01/06/2015

Technical manager: Stephanie MOROT-BIZOT

Signature :

Validations and controls

Suspension of validation Nv0			Experimental conditions control (A)			Control of neutralization (B)			Validation of dilution-neutralization method product concentration (C) 100% 15 min		
Vc1	57 (30+27)	$\bar{x}$ = 54,5	Vc1	51 (27+24)	$\bar{x}$ = 47,5	Vc1	46 (26+20)	$\bar{x}$ = 45,5	Vc1	40 (22+18)	$\bar{x}$ = 37,5
Vc2	52 (28+24)		Vc2	44 (23+21)		Vc2	45 (21+24)		Vc2	35 (18+17)	
30 ≤ $\bar{x}$ de Nv0 ≤160 ☒ yes no			$\bar{x}$ de A est ≥0,5 × $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de B ≥ 0,5× $\bar{x}$ de Nv0 ☒ yes no			$\bar{x}$ de C ≥ 0,5 × $\bar{x}$ de Nv0 ☒ yes no		

Test suspension and test

TRIAL SUSPENSION N	**N**	**Vc1**	**Vc2**	N = 2,50 x 10^9 lg N = 9,40 9,17 ≤ lg N ≤ 9,70? ×yes no
	10^{-7}	251	240	
	10^{-8}	25	25	

WATER CONTROL Nw		**Vc1**	**Vc2**	Nw = $\bar{x}$ x 10 = 4,5x 10^6 lg Nw = 6,65 6,15 ≤ log Nw ≤ (log N-1,3)? ×yes no
	10^{-4}	49	45	
	10^{-5}	3	2	

	10^0		10^{-1}		10^{-2}		10^{-3}		lg Na = lg ($\overline{x}$ x 10)	lg R = lg Nw – lg Na	CONTACT TIME
	Vc1	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**	**Vc1**	**Vc2**			
PRODUCT 100%	68	66	6	8	0	0	0	0	2,83	3,82	5 min
	46	41	1	3	0	0	0	0	2,64	**4,01**	10 min
	20	24	2	2	0	0	0	0	2,34	**4,31**	15 min
	0	0	0	0	0	0	0	0	<2,15	**>4,50**	60 min

7 TECHNICAL APPENDIX

MEDIA

- Middlebrook broth 7H9, FLUKA, réf. 100957898, batch n° BCBC4788
- ADC 10%, FLUKA, réf. 101007527, batch n° BCBD4192
- Middlebrook media and Cohn 7H10 SIGMA-ALDRICH, réf. M0303, batch n° BCBK3491V
- OADC 10%, FLUKA, réf. 100962567, batch n° BCBC5497

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

STOP SOLUTION

Ingredients in grams per litre of distilled water:

Sodium thiosulfate, Sigma Aldrich, ref. 7249, batch n° BCBD0584V ---------- 20 g

ORGANIC SOIL LOAD:
Bovine serum albumin powder, Dominique Dutscher, ref.871001, batch D1304039

GLASS CARRIERS – frosted glass 15 x 60 mm, 1 mm thick – Thermo scientific/ Menzel-Gläser – ref. 100 OTM, batch n°01 1794389.

TEST REPORT

DETERMINATION OF THE SPORICIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE ON 14347 STANDARD

Delivered to: Ms CHAKCHOUK

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

Date of request: 05/12/2015

Study references: n°140D10-2015-01

SPORICIDAL TESTS:

According to the European standard EN 14347 (August 2005) – Chemical disinfectants and antiseptics. Basic sporicidal activity.

Tests using the F010474V1 product against 1 reference strain: *Bacillus subtilis.*

This test report included 12 pages.

Study completion date: 07/10/2015

Stephanie MOROT - BIZOT
PhD in Microbiology
Study Director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

F010474V1

Batch# : n° 4494B01

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: peracetic acid

Appearance of the product: clear.

Product diluent recommended by the manufacturer for use: none, ready-to-use product.

Date of delivery of the product: 05/22/2015

Date of tests: 06/15/2015 to 06/26/2015

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 80.0%

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 5 min – 10 min – 15 min – 30 min

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

Diluent used for the assays: distilled water

Diluent used for the bacterial suspensions: sterile trypton salt solution

Bacterial strains: *Bacillus subtilis* CIP 55.62 batch 17510 - Institut Pasteur

Media and growth conditions: TSA (Trypton Soy Agar) and sheep blood agar, at 37°C ± 1°C.

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

4 VALIDATION AND RESULTS

See sheets of results.

Repeat counts of spore suspensions and calculation of standard deviations:

Bacillus subtilis (CFU/mL)

n1 = $6{,}53.10^8$
n2 = $5{,}25.10^8$
n3 = $5{,}19.10^8$
n4 = $6{,}20.10^8$
n5 = $6{,}33.10^8$

$\xi = 5{,}90.10^8$ UFC/mL

$s = 6{,}32.10^7$ UFC/mL

The F010474V1 product :

– Is active on *Bacillus subtilis* when used from the 100% concentration (final concentration 80%), for 10 min of exposure time, because R = 4,29 log (trial) and R' = 4,38 log (repetition)

5 CONCLUSIONS

According to the EN 14347 standard (August 2005), the F010474V1, batch n°4494B01 product :

– **Demonstrated a basic sporicidal activity on the reference strain *Bacillus subtilis* when used at the concentration of 100% (final concentration 80%), for 10 min of contact time, at 20 °C.**

SHEET OF RESULTS 1 -
Bacillus subtilis

STANDARD : EN 14347, phase 1 step 1
PRODUCT: F010474V1
Batch n° : 4494B01

METHOD ☒ Pour plating
☐ Spread plating
☒ Number of plates /mL: 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%) + saponin (30 g/L) + histidine (1 g/L).

Trial temperature : 20°C.

STRAIN : *Bacillus subtilis* CIP 55.62

Incubation temperature : 37°C ± 1°C

STUDY N° 140D10-2015-01 DATE OF TRIALS: 06/22/2015 and 06/23/2015

Study director : Ms Stephanie MOROT-BIZOT Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validation and controls

$\xi = 5{,}90.10^{8}$ UFC/ml $s = 6{,}32.10^{7}$ UFC/ml

	Trial suspension N1			Trial suspension N2			Suspension of validation Nv	
	Vc1	**Vc2**		**Vc1**	**Vc2**		**Vc1**	**Vc2**
10^{-6}	>330	>330	**10^{-0}**	>330	>330	**10^{-2}**	>330	>330
10^{-7}	59	63	**10^{-1}**	48	49	**10^{-3}**	55	59
10^{-8}	6	6	**10^{-2}**	5	5	**10^{-4}**	4	7
N1	$6{,}1.10^{8}$		**N2**	$4{,}9.10^{2}$		**Nv**	$5{,}7.10^{4}$	
log N1	8,79		**log N2**	2,69		**log Nv**	4,76	
8,48 ≤ log N1 ≤ 9,00 ? x yes □ no			2,48 ≤ log N2 ≤ 3,00 ? x yes □ no			4,48 ≤ log Nv ≤ 5,00 ? x yes □ no		

Validations and trials

	Neutralizer control B		Cytotoxicity control on long run
	Vc1	**Vc2**	Visible growth
10^{-2}	>330	>330	x yes □ no
10^{-3}	>330	>330	
10^{-4}	77	70	
B	$7{,}4.10^{7}$		
log B	7,87		
7,48 ≤ log B ≤ 8,00 ? x yes □ no			

Validation of the C method with and without neutralizer

Control-tube of the long run cytotoxicity of the neutralizer: growth

	Validation of the C method					
	WITH NEUTRALIZER			WITHOUT NEUTRALIZER		
	C1	**Vc1**	**Vc2**	**C4**	**Vc1**	**Vc2**
Product concentration	**10^{0} (TNO)**	>330	>330	**10^{0} (TNO)**	0	0
	10^{-1}	78	75	**10^{-1}**	0	0
	10^{-2}	7	8	**10^{-2}**	0	0
NEAT (80% final)	**C1**	$7{,}7.10^{4}$		**C4**	$1{,}4.10^{3}$	
	log C1	4,88		**log C4**	3,15	
	4,48 ≤ log C1 ≤ 5,00 ? x yes □ no					
	C2	**Vc1**	**Vc2**	**C5**	**Vc1**	**Vc2**
Product concentration	**10^{0} (TNO)**	>330	>330	**10^{0} (TNO)**	35	30
	10^{-1}	73	70	**10^{-1}**	3	0
	10^{-2}	7	11	**10^{-2}**	0	0
50%	**C2**	$7{,}2.10^{4}$		**C5**	$3{,}3.10^{3}$	
	log C2	4,85		**log C5**	3,51	
	4,48 ≤ log C2 ≤ 5,00 ? x yes □ no					

TRIALS

TRIALS							
Product concentration 80%		Vc1	Vc2				
	10^0 (TNO)	66	83				
	10^{-1}	12	8				
	10^{-2}	1	1				
5 min	10^{-3}	0	0				
	Na	$7,5.10^3$					
	log Na	3,87					
	LOG R	3,79					
Product concentration 80%		Vc1	Vc2	Product concentration 80%		Vc1	Vc2
	10^0 (TNO)	23	24		10^0 (TNO)	0	0
	10^{-1}	1	2		10^{-1}	0	0
	10^{-2}	0	0		10^{-2}	0	0
	10^{-3}	0	0		10^{-3}	0	0
10 min	Na	$2,4.10^3$		**15 min**	Na	$1,4.10^3$	
	log Na	3,37			log Na	3,15	
	LOG R	**4,29**			LOG R	**4,52**	
Product concentration 80 %		Vc1	Vc2			Vc1	Vc2
	10^0 (TNO)	0	0		10^{-2}	>330	>330
	10^{-1}	0	0		10^{-3}	>330	>330
	10^{-2}	0	0	**Water control Nw**	10^{-4}	44	48
	10^{-3}	0	0		Nw	$4,6.10^7$	
30 min	Na	$1,4.10^3$			log Nw	**7,66**	
	log Na	3,15			7,48 ≤ log Nw ≤ 8,00 ?		
	LOG R	**4,52**			x yes □ no		

The TNO showed a viisble growth after inoculation ☒ yes ☐ no

REPETITION

Validation and controls

$\xi = 5{,}90.10^{8}$ UFC/ml $s = 6{,}32.10^{7}$ UFC/ml

	Trial suspension N1			Trial suspension N2			Suspension of validation Nv	
	Vc1	**Vc2**		**Vc1**	**Vc2**		**Vc1**	**Vc2**
10^{-6}	>330	>330	**10^{-0}**	>330	>330	**10^{-2}**	>330	>330
10^{-7}	44	53	**10^{-1}**	50	48	**10^{-3}**	55	50
10^{-8}	8	3	**10^{-2}**	4	5	**10^{-4}**	7	6
N1	$4{,}9.10^{8}$		**N2**	$4{,}9.10^{2}$		**Nv**	$5{,}3.10^{4}$	
log N1	8,69		**log N2**	2,69		**log Nv**	4,72	
8,48 ≤ log N1 ≤ 9,00 ? x yes □ no			2,48 ≤ log N2 ≤ 3,00 ? x yes □ no			4,48 ≤ log Nv ≤ 5,00 ? x yes □ no		

Validations and trials

	Neutralizer control B		Cytotoxicity control on long run
	Vc1	**Vc2**	Visible growth x yes □ no
10^{-3}	>330	>330	
10^{-4}	>330	>330	
10^{-5}	63	63	
B	$6{,}3.10^{7}$		
log B	7,80		
7,48 ≤ log B ≤ 8,00 ? x yes □ no			

Validation of the C method with and without neutralizer

Control-tube of the long run cytotoxicity of the neutralizer: growth

	Validation of the C method					
	WITH NEUTRALIZER			WITHOUT NEUTRALIZER		
	C1	**Vc1**	**Vc2**	**C4**	**Vc1**	**Vc2**
Product concentration	**10^0 (TNO)**	>330	>330	**10^0 (TNO)**	0	0
	10^{-1}	84	80	**10^{-1}**	0	0
	10^{-2}	8	9	**10^{-2}**	0	0
NEAT (80% final)	**C1**	$8{,}2.10^4$		**C4**	$1{,}4.10^3$	
	log C1	4,91		**log C4**	3,15	
	4,48 ≤ log C1 ≤ 5,00 ? x yes □ no					
	C2	**Vc1**	**Vc2**	**C5**	**Vc1**	**Vc2**
Product concentration	**10^0 (TNO)**	>330	>330	**10^0 (TNO)**	2	12
	10^{-1}	81	80	**10^{-1}**	0	0
	10^{-2}	7	9	**10^{-2}**	0	0
50%	**C2**	$8{,}1.10^4$		**C5**	$1{,}4.10^3$	
	log C2	4,91		**log C5**	3,15	
	4,48 ≤ log C2 ≤ 5,00 ? x yes □ no					

TRIALS

TRIALS							
Product concentration 80%		Vc1	Vc2				
	10^0 (TNO)	90	81				
	10^{-1}	6	8				
	10^{-2}	0	0				
5 min	10^{-3}	0	0				
	Na	$8,6.10^3$					
	log Na	3,93					
	LOG R	3,70					
Product concentration 80%		Vc1	Vc2	Product concentration 80%		Vc1	Vc2
	10^0 (TNO)	20	16		10^0 (TNO)	0	0
	10^{-1}	0	1		10^{-1}	0	0
	10^{-2}	0	0		10^{-2}	0	0
	10^{-3}	0	0		10^{-3}	0	0
10 min	Na	$1,8.10^3$		**15 min**	Na	$1,4.10^3$	
	log Na	3,26			log Na	3,15	
	LOG R	**4,38**			LOG R	**4,49**	
Product concentration 80 %		Vc1	Vc2			Vc1	Vc2
	10^0 (TNO)	0	0		10^{-2}	>330	>330
	10^{-1}	0	0		10^{-3}	>330	>330
	10^{-2}	0	0	**Water control Nw**	10^{-4}	40	46
	10^{-3}	0	0		Nw	$4,3.10^7$	
30 min	Na	$1,4.10^3$			log Nw	7,63	
	log Na	3,15			7,48 ≤ log Nw ≤ 8,00 ?		
	LOG R	**4,49**			x yes □ no		

The TNO showed a viisble growth after inoculation ☒ yes ☐ no

Legend :

Vc = number of colonies counted on plates
ξ = average value
s = standard deviation
$\bar{x}$ = average of Vc1 and Vc2
R = reduction (lg R = lg Nw – lg Na)

Control of the bacterial spore suspension with the reference substances

		Vc1	Vc2				
	10^0 (TNO)	331	331	**Na**	**log Na**	**Growth on TNO**	**R**
Glutaraldehyde 3% 30min *B.subtilis*	**10^{-1}**	80	85	$8{,}3.10^4$	4,92	YES	2,64
	10^{-2}	6	8				
	10^{-3}	0	0				
	10^0 (TNO)	331	331	Na	**log Na**	**Growth on TNO**	**R**
Peracetic acid 0,05% 15 min *B.subtilis*	**10^{-1}**	331	331	$1{,}6.10^5$	5,19	YES	2,37
	10^{-2}	16	15				
	10^{-3}	0	0				
	10^{-2}	331	331	**Nw**	**log Nw**		
Nw BS	**10^{-3}**	331	331	$3{,}6.10^7$	7,56		
	10^{-4}	34	38				

6 TECHNICAL APPENDIX

Media:

TSA (Trypton Soy Agar), Dominique Dutscher, ref. n° 777410, batch n° 211061

Blood sheep agar:

- Hemoglobin, OXOÏD, ref. n° SR0051E, batch n° 30964000
- Blood agar, Laboratoires CONDA, ref.1108, batch n°1281----------10 %

Sporulation agar:

- Pepton, Laboratoires CONDA, ref.1606, batch n°190525----------10 g/L
- Yeast extract, Laboratoires CONDA, ref.1702, batch n°000231----------2 g/L
- Manganese sulfate, SIGMA-ALDRICH, ref. M7634, batch n° 030M0143---------0,04 g/L
- Agar, Laboratoires CONDA, ref.1800, batch n° 15100158 ----------15 g/L
- Water ----------q.s.p 1 L

Diluent

Trypton-Sel Solution (TS)

Ingredients in grams per litre of distilled water:

- Trypton, CONDA, ref. 1612, batch n ° 091229 ----------1,00 g/L
- Sodium chloride, DUTSCHER, ref 19032391, batch n° 836751 ----------8,50 g/L

pH after autoclaving at 25 °C: 7.0 ± 0.2

Stop solution

Ingredients per liter of PBS buffer:

- Tween 80, Sigma Aldrich, ref 59924, lot BCBJ6978V ---------- 30 g/L
- Egg yolk ---------- 3 g/L
- Histidin, Alfa Aesar, ref. A17627, batch n° 10114426 ---------- 1 g

Sterilized by filter filtration on 0,45 µm; pH at 25°C : 7,4 ± 0,1

TEST REPORT

DETERMINATION OF THE SPORICIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE ON 14347 STANDARD

Delivered to: Ms CHAKCHOUK

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

Date of request: 07/17/2014

Study references: n°295D11-2014-02

SPORICIDAL TESTS:

According to the European standard EN 14347 (August 2005) – Chemical disinfectants and antiseptics. Basic sporicidal activity.

Tests using the F010474V1 product against 1 reference strain: *Bacillus cereus.*

This test report included 11 pages.

Study completion date: 01/31/2015

Stephanie MOROT - BIZOT
PhD in Microbiology
Study Director

SUMMARY

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
18, rue Alain SAVARY
25000 BESANÇON
FRANCE

2 PRODUCT IDENTITY

F010474V1

Batch# : n° 4494

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: peracetic acid

Appearance of the product: clear.

Product diluent recommended by the manufacturer for use: none, ready-to-use product.

Date of delivery of the product: 12/02/2014

Date of tests: 12/04/2014 to 12/31/2014

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 80.0%

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 5 min – 10 min – 15 min – 30 min

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

Diluent used for the assays: distilled water

Diluent used for the bacterial suspensions: sterile trypton salt solution

Bacterial strains: *Bacillus cereus* CIP 105151 batch 6210 - Institut Pasteur

Media and growth conditions: TSA (Trypton Soy Agar), at 37°C ± 1°C.

Product stability: limpid solution with organic soil load

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

4 VALIDATION AND RESULTS

See sheets of results.

Repeat counts of spore suspensions and calculation of standard deviations:

Bacillus cereus (CFU/ml)

n1 = $6{,}95.10^8$

n2 = $4{,}24.10^8$

n3 = $6{,}14.10^8$

n4 = $5{,}24.10^8$

n5 = $6{,}19.10^8$

$\xi = 5{,}75.10^8$ CFU/mL

s = $1{,}04.10^8$ CFU/mL

The F010474V1 product :

– Is active on *Bacillus cereus* when used from the 100% concentration (final concentration 80%), for 10 min of exposure time, because R > 4,06 log (trial) and R' > 4,04 log (repetition)

5 CONCLUSIONS

According to the EN 14347 standard (August 2005), the F010474V1, batch n°4494 product :

– **Demonstrated a basic sporicidal activity on the reference strain *Bacillus cereus* when used at the concentration of 100% (final concentration 80%), for 10 min of contact time, at 20 °C.**

SHEET OF RESULTS 1 (TRIAL) -
Bacillus cereus

STANDARD : EN 14347, phase 1 step 1
PRODUCT: F010474V1
Batch n° : 4494

METHOD ☒ Pour plating
☐ Spread plating
☒ Number of plates /mL: 1

Neutralizer: Polysorbate 80 (30g/l) + Egg yolk (5%) + saponin (30 g/L) + histidine (1 g/L).

Trial temperature : 20°C.

STRAIN : *Bacillus cereus* CIP 105151

Incubation temperature : 37°C ± 1°C

STUDY N° 295D11-2014-02 DATE OF TRIALS: 12/17/2014 and 12/22/2014

Study director : Ms Stephanie MOROT-BIZOT Signature :

Diluent used: distilled water

Appearance of the product's dilutions : clear

Validation and controls

$\xi = 5{,}75.10^8$ $s = 1{,}04.10^8$

	Trial suspension N1			Trial suspension N2			Suspension of validation Nv	
	Vc1	**Vc2**		**Vc1**	**Vc2**		**Vc1**	**Vc2**
10^{-6}	>330	>330	**10^{-0}**	>330	>330	**10^{-2}**	>330	>330
10^{-7}	41	47	**10^{-1}**	54	50	**10^{-3}**	44	41
10^{-8}	6	4	**10^{-2}**	3	3	**10^{-4}**	5	4
N1	$4{,}4.10^8$		**N2**	$5{,}2.10^2$		**Nv**	$4{,}3.10^4$	
log N1	8,64		**log N2**	2,72		**log Nv**	4,63	
8,48 ≤ log N1 ≤ 9,00 ? x yes □ no			2,48 ≤ log N2 ≤ 3,00 ? x yes □ no			4,48 ≤ log Nv ≤ 5,00 ? x yes □ no		

Validations and trials

	Neutralizer control B		Cytotoxicity control on long run
	Vc1	**Vc2**	Visible growth x yes □ no
10^{-2}	>330	>330	
10^{-3}	>330	>330	
10^{-4}	70	69	
B	$7{,}0.10^{7}$		
log B	7,84		
7,48 ≤ log B ≤ 8,00 ? x yes □ no			

Validation of the C method with and without neutralizer

Control-tube of the long run cytotoxicity of the neutralizer: growth

	Validation of the C method					
	WITH NEUTRALIZER			WITHOUT NEUTRALIZER		
Product concentration	**C1**	**Vc1**	**Vc2**	**C4**	**Vc1**	**Vc2**
	10^{0} (TNO)	>330	>330	**10^{0} (TNO)**	22	21
	10^{-1}	68	68	**10^{-1}**	2	0
	10^{-2}	6	6	**10^{-2}**	0	0
NEAT (80%)	**C1**	$6{,}8.10^{4}$		**C4**	$2{,}2.10^{3}$	
	log C1	4,83		**log C4**	3,33	
	4,48 ≤ log C1 ≤ 5,00 ? x yes □ no					
Product concentration	**C2**	**Vc1**	**Vc2**	**C5**	**Vc1**	**Vc2**
	10^{0} (TNO)	>330	>330	**10^{0} (TNO)**	>330	>330
	10^{-1}	63	62	**10^{-1}**	59	54
	10^{-2}	6	5	**10^{-2}**	6	5
50%	**C2**	$6{,}3.10^{4}$		**C5**	$5{,}7.10^{4}$	
	log C2	4,80		**log C5**	4,75	
	4,48 ≤ log C2 ≤ 5,00 ? x yes □ no					

TRIAL

TRIAL							
		Vc1	Vc2			Vc1	Vc2
Product concentration	10^0 (TNO)	0	0	Product concentration	10^0 (TNO)	33	36
	10^{-1}	0	0		10^{-1}	1	3
	10^{-2}	0	0		10^{-2}	0	0
	10^{-3}	0	0		10^{-3}	0	0
15 min and 60 min	Na	$1,4.10^3$		**10 min**	Na	$3,5.10^3$	
	log Na	3,15			log Na	3,54	
	LOG R	**4,45**			LOG R	**4,06**	
		Vc1	Vc2			Vc1	Vc2
Product concentration	10^0 (TNO)	>330	>330		10^{-2}	>330	>330
	10^{-1}	89	102		10^{-3}	>330	>330
	10^{-2}	7	9	**Water control Nw**	10^{-4}	41	38
	10^{-3}	0	1		Nw	$4,0.10^7$	
5 min	Na	$9,6.10^4$			log Nw	**7,60**	
	log Na	4,98			7,48 ≤ log Nw ≤ 8,00 ?		
	LOG R	**2,62**			x yes □ no		

The TNO showed a viisble growth after inoculation ☒ yes ☐ no

REPETITION

Validation and controls

$\xi = 5,75.10^8$ $s = 1,04.10^8$

	Trial suspension N1			Trial suspension N2			Suspension of validation Nv	
	Vc1	Vc2		Vc1	Vc2		Vc1	Vc2
10^{-6}	>330	>330	10^{-0}	>330	>330	10^{-2}	>330	>330
10^{-7}	40	41	10^{-1}	51	53	10^{-3}	59	51
10^{-8}	4	4	10^{-2}	2	4	10^{-4}	3	5
N1	$4,1.10^8$		N2	$5,2.10^2$		Nv	$5,5.10^4$	
log N1	8,61		log N2	2,72		log Nv	4,74	
8,48 ≤ log N1 ≤ 9,00 ? x yes □ no			2,48 ≤ log N2 ≤ 3,00 ? x yes □ no			4,48 ≤ log Nv ≤ 5,00 ? x yes □ no		

Validations and trials

	Neutralizer control B		Cytotoxicity control on long run
	Vc1	**Vc2**	Visible growth x yes □ no
10^{-3}	>330	>330	
10^{-4}	>330	>330	
10^{-5}	50	43	
B	$4{,}7.10^{7}$		
log B	7,67		
7,48 ≤ log B ≤ 8,00 ? x yes □ no			

Validation of the C method with and without neutralizer

Control-tube of the long run cytotoxicity of the neutralizer: growth

	Validation of the C method					
	WITH NEUTRALIZER			**WITHOUT NEUTRALIZER**		
Product concentration	**C1**	**Vc1**	**Vc2**	**C4**	**Vc1**	**Vc2**
	10^{0} (TNO)	>330	>330	**10^{0} (TNO)**	>330	>330
	10^{-1}	74	73	**10^{-1}**	78	77
	10^{-2}	6	7	**10^{-2}**	7	10
NEAT	**C1**	$7{,}4.10^{4}$		**C4**	$7{,}8.10^{4}$	
	log C1	4,87		**log C4**	4,89	
	4,48 ≤ log C1 ≤ 5,00 ? x yes □ no					
Product concentration	**C2**	**Vc1**	**Vc2**	**C5**	**Vc1**	**Vc2**
	10^{0} (TNO)	>330	>330	**10^{0} (TNO)**	>330	>330
	10^{-1}	81	80	**10^{-1}**	92	90
	10^{-2}	8	7	**10^{-2}**	9	10
50%	**C2**	$8{,}1.10^{4}$		**C5**	$9{,}1.10^{4}$	
	log C2	4,91		**log C5**	4,96	
	4,48 ≤ log C2 ≤ 5,00 ? x yes □ no					

TRIALS

TRIALS							
		Vc1	Vc2			Vc1	Vc2
Product concentration	**10^0 (TNO)**	1	1	Product concentration	**10^0 (TNO)**	>330	>330
	10^{-1}	0	0		**10^{-1}**	89	89
	10^{-2}	0	0		**10^{-2}**	10	11
	10^{-3}	0	0		**10^{-3}**	2	0
15 min and 60 min	**Na**	$1,4.10^3$		**5 min**	**Na**	$8,9.10^4$	
	log Na	3,15			**log Na**	4,95	
	LOG R	**4,53**			**LOG R**	**2,72**	
		Vc1	**Vc2**			**Vc1**	**Vc2**
Product concentration	**10^0 (TNO)**	44	41	**WATER CONTROL Nw**	**10^{-2}**	>330	>330
	10^{-1}	4	5		**10^{-3}**	>330	>330
	10^{-2}	0	0		**10^{-4}**	45	49
	10^{-3}	0	0		**Nw**	$4,7.10^7$	
10 min	**Na**	$4,3.10^3$			**log Nw**	7,67	
	log Na	3,63			7,48 ≤ log Nw ≤ 8,00 ?		
	LOG R	**4,04**			x yes □ no		

The TNO showed a viisble growth after inoculation ☒ yes ☐ no

Legend :

Vc = number of colonies counted on plates
ξ = average value
s = standard deviation
$\bar{x}$ = average of Vc1 and Vc2
R = reduction (lg R = lg Nw – lg Na)

Control of the bacterial spore suspension with the reference substances

		Vc1	Vc2				
Glutaraldehyde 1% 30min *B.cereus*	**10^0 (TNO)**	331	331	**Na**	**Log Na**	**Growth on TNO**	**R**
	10^{-1}	43	44	$4{,}4.10^4$	4,64	YES	2,89
	10^{-2}	5	4				
	10^{-3}	0	0				
Peracetic acid 0,1% 15min B.cereus	**10^0 (TNO)**	331	331	**Na**	**Log Na**	**Growth on TNO**	**R**
	10^{-1}	331	331	2,7.106	6,42	YES	1,11
	10^{-2}	331	331				
	10^{-3}	30	23				
Nw BC	**10^{-2}**	331	331	**Nw**	**Log Nw**		
	10^{-3}	331	331	$3{,}4.10^7$	7,53		
	10^{-4}	34	34				

6 TECHNICAL APPENDIX

Media:

TSA (Trypton Soy Agar), ThermoFisher, ref. n° 1176-8822, batch n° 3298495

Blood sheep agar:

- Hemoglobin, Analytic Lab, ref. 08449, batch n° bcbj3984V
- Blood agar, Laboratoires CONDA, ref.1108, batch n°1281----------10 %

Sporulation agar:

- Pepton, Laboratoires CONDA, ref.1606, batch n°190525----------10 g/L
- Yeast extract, Laboratoires CONDA, ref.1702, batch n°000231----------2 g/L
- Manganese sulfate, SIGMA-ALDRICH, ref. M7634, batch n° 030M0143---------0,04 g/L
- Agar, Laboratoires CONDA, ref.1800, batch n° 15100158 ----------15 g/L
- Water ----------q.s.p 1 L

Diluent

Trypton-Sel Solution (TS)

Ingredients in grams per litre of distilled water:

- Trypton, CONDA, ref. 1612, batch n ° 091229 ----------1,00 g/L
- Sodium chloride, DUTSCHER, ref 19032391, batch n° 836751 ----------8,50 g/L

pH after autoclaving at 25 °C: 7.0 ± 0.2

Stop solution

Ingredients per liter of PBS buffer:

- Tween 80, Sigma Aldrich, ref 59924, lot BCBJ6978V ---------- 30 g/L
- Egg yolk ---------- 3 g/L
- Histidin, Alfa Aesar, ref. A17627, batch n° 10114426 ---------- 1 g

Sterilized by filter filtration on 0,45 µm; pH at 25°C : 7,4 ± 0,1

Toulouse, September 15th 2021

TEST REPORT N°21-1730M2

STUDY 21-2884

This report supersedes the precedent one (September 3rd 2021)

NF EN 17126 (December 2018)
QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF SPORICIDAL ACTIVITY IN THE MEDICAL AREA -
Disinfection of medical devices
Obligatory conditions
Clean condition - *B. subtilis* and *B. cereus*

Client

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Assay Laboratory

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Pr **Christine ROQUES** Assay Manager	Dr **Jocelyne BACARIA** Quality Manager
PO Catherine FEUILLOLAY Signature numérique de Catherine FEUILLOLAY Date : 2021.09.15 12:20:09 +02'00'	Jocelyne BACARIA Signature numérique de Jocelyne BACARIA Date : 2021.09.16 08:05:44 +02'00'

The COFRAC accreditation only attests the capability of the laboratory for assays covered by the accreditation.
COFRAC is a signatory of the multilateral recognition agreements of EA[1] and/or of ILAC[2] and/or of IAF[3] for testing activities.

[1] European co-operation for Accreditation
[2] International Laboratory Accreditation Cooperation
[3] International Accreditation Forum

FIVI_EN17126_09.21_EW

I - IDENTIFICATION OF ASSAY LABORATORY

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FRANCE

II - IDENTIFICATION OF TEST PRODUCT

Product :	**F010474V1**
Batch :	7238
Expiry date:	Not precised
Date of receipt :	Feb/18/2021
Internal code :	**21-2884-4**
Active substances :	Peracetic acid
Manufacturer :	FRANKLAB
Period of testing :	March - May 2021

Storage conditions during the period of testing : Room temperature

III - TEST

Method : **Dilution – neutralization**

Neutralizer 1 : Polysorbate 80 (10%), Saponin (2%), Lecithin (2%), sodium thiosulfate (0,5%), QSP Trypcase Soy broth (internal preparation - Batches 1161 Exp. March/16/2021 and 1166 Exp. Apr/23/2021)

Neutralizer 2 : Aqueous solution of sodium pyruvate (3%), Polysorbate 80 (3%), (internal preparation - Batch 10183 Exp. March/23/2021)

Membrane filtration

Nitrocellulose membranes 0.45µm (Millipore - batches F0MB14755C et F0SB62670C)

Count(s) per ml : 1 or 2 for $N/10^{-5}$ and $N/10^{-6}$ (modified method)

Appearance of the product : Liquid, clear

Aspect of solutions under assay : Clear

IV - EXPERIMENTAL CONDITIONS

Product diluent : Water for Injectable Preparations

Interfering substance: 0,3 g/L bovine albumin (clean conditions)

Obligatory conditions :

Tests-organisms :	*Bacillus subtilis* CIP 52.62 *Bacillus cereus* CIP 105151
Concentrations of the product:	**97%, 80%** and **0,1% (V/V)**
Test temperature :	20°C ± 1°C
Contact time :	10 minutes ± 10 seconds

Incubation temperature : 36°C ± 1°C
Aspect of solutions during assay : Clear for all the concentrations

FIVI - EN 17126-09-21-EN

V - RESULTS

BACILLUS SUBTILIS CIP 52.62 - Neutralizer 1

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST		
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 97% C	N			Final concentration of product % (V/V)	
					10^{-6}	10^{-7}		Contact time	97%
Vc1-Vc2	Nvo 142-157 NvB 140-150	119 - 150	135 - 157	0 - 0	447-537	37 - 49	Vc1 - Vc2	10 minutes	-
$\bar{x}$	Nvo 150 NvB 145	135	146	0	$\bar{x}$ wm = 486,36.10^6 lg N = 8,69			10 minutes	-
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 05 $\bar{x}$ of Nv_0	$\bar{x}$ of B ≥ 0, 05 $\bar{x}$ of Nv_B	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nv_0	N/100= 486,36.10^4 lg N/100 = 6,69			10 minutes	-
					6,17≤lg N/100 ≤ 6,70		lg Na	10 minutes	-
							lg R	10 minutes	-

Date of the test: Feb/25/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-6}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 - lg Na)

UNVALID NEUTRALIZATION

BACILLUS SUBTILIS CIP 52.62 – Neutralizer 1

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST			
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 80% C	N			Final concentration of product % (V/V)		
					10^{-5}	10^{-6}		Contact time	80%	0,1%
Vc1-Vc2	Nvo 142-157 NvB 140-150	145 - 150	135 - 157	0 - 0	447-537	37 - 49	Vc1 - Vc2	10 minutes	-	-
$\bar{x}$	Nvo 150 NvB 145	148	146	0	$\bar{x}$ wm = $486,36.10^5$ lg N = 7,69			10 minutes	-	-
	$\bar{x}$ de Nvo et NvB entre 30 et 160	$\bar{x}$ de A ≥ 0,5 $\bar{x}$ de Nvo	$\bar{x}$ de B ≥ 0,5 $\bar{x}$ de NvB	$\bar{x}$ de C ≥ 0,5 $\bar{x}$ de Nvo	N/10= $486,36.10^4$ lg N/10 = 6,69			10 minutes	-	-
					6,17≤lg N/10 ≤ 6,70		lg Na	10 minutes	-	-
							lg R	10 minutes	-	-

Date of the test: Feb/25/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-5}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

UNVALID NEUTRALIZATION

BACILLUS SUBTILIS CIP 52.62 – Neutralizer 2

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST		
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 97% C	N			Final concentration of product % (V/V)	
					10^{-6}	10^{-7}		Contact time	97%
Vc1-Vc2	Nvo 111 - 120	-	124 - 126	2 - 5	-	-	Vc1 - Vc2	10 minutes	-
$\bar{x}$	Nvo 116	-	125	4	-			10 minutes	-
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 05 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 05 $\bar{x}$ of Nv_B	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	-			10 minutes	-
					6,17≤lg N/100 ≤ 6,70		lg Na	10 minutes	-
							lg R	10 minutes	-

Date of the test: March/03/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-6}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

UNVALID NEUTRALIZATION

BACILLUS SUBTILIS CIP 52.62 – Neutralizer 2

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST			
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 80% C	N			Final concentration of product % (V/V)		
					10^{-5}	10^{-6}		Contact time	80%	0,1%
Vc1-Vc2	Nvo 111 - 120	-	124 - 126	116 - 129	-	-	Vc1 – Vc2	10 minutes	-	-
$\bar{x}$	Nvo 116	-	125	123	-			10 minutes	-	-
	$\bar{x}$ de Nvo et NvB entre 30 et 160	$\bar{x}$ de A ≥ 0,5 $\bar{x}$ de Nvo	$\bar{x}$ de B ≥ 0,5 $\bar{x}$ de NvB	$\bar{x}$ de C ≥ 0,5 $\bar{x}$ de Nvo	-			10 minutes	-	-
					6,17≤lg N/10 ≤ 6,70		lg Na	10 minutes	-	-
							lg R	10 minutes	-	-

Date of the test: March/03/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-5}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

UNVALID NEUTRALIZATION

BACILLUS SUBTILIS CIP 52.62 - Membrane filtration

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST		
	Validation suspension Nvo	Experimental conditions control A	Filtration control B	Method validation Product conc. 97% C	N			Final concentration of product % (V/V)	
					10^{-6}	10^{-7}		Contact time	97%
Vc1-Vc2	Nvo 147-152	68 - 93	84 - 93	106 - 107	417-427	39 - 47	Vc1 - Vc2	10 minutes	10^{0} 0 - 0 10^{-1} 0 - 0
$\bar{x}$	Nvo 150	81	89	107	$\bar{x}$ wm = $422{,}73.10^{6}$ lg N = 8,63			10 minutes	< 14
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0,05 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,05 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/100= $422{,}73.10^{4}$ lg N/100 = 6,63			10 minutes	< 140
					6,17≤lg N/100 ≤ 6,70		lg Na	10 minutes	< 2,15
							lg R	10 minutes	> 4,48

Date of the test: March/09/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-6}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg No - lg Na)

BACILLUS SUBTILIS CIP 52.62 – Membrane filtration

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST			
	Validation suspension Nvo	Experimental conditions control A	Filtration control B	Method validation Product conc. 80% C	N			Final concentration of product % (V/V)		
					10^{-5}	10^{-6}		Contact time	80%	0,1%
Vc1-Vc2	Nvo 147-152	80 - 99	84 - 93	92 - 106	417-427	39 - 47	Vc1 – Vc2	10 minutes	10^{0} 0 - 0 10^{-1} 0 - 0	10^{0} >330->330 10^{-1} >330->330
$\bar{x}$	Nvo 150	90	89	99	$\bar{x}$ wm = $427,73.10^{5}$ lg N = 7,63			10 minutes	< 14	>3300
	$\bar{x}$ de Nvo et NvB entre 30 et 160	$\bar{x}$ de A ≥ 0,5 $\bar{x}$ de Nvo	$\bar{x}$ de B ≥ 0,5 $\bar{x}$ de NvB	$\bar{x}$ de C ≥ 0,5 $\bar{x}$ de Nvo	N/100= $427,73.10^{4}$ lg N/10 = 6,63			10 minutes	< 140	> $3,3.10^{4}$
					6,17≤lg N/10 ≤ 6,70		lg Na	10 minutes	< 2,15	> 4,52
							lg R	10 minutes	> 4,48	< 2,11

Date of the test: March/09/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-5}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

BACILLUS CEREUS CIP 105.151 – Neutralizer 1

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST		
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 97% C	N			Final concentration of product % (V/V)	
					10^{-6}	10^{-7}		Contact time	97%
Vc1-Vc2	Nvo 21 - 25 NvB 43 - 46	-	48 - 52	0 - 0	71 - 59	7 - 17	Vc1 - Vc2	10 minutes	-
$\bar{x}$	Nvo 23 NvB 45	-	50	0	$\bar{x}$ wm = $70{,}00.10^6$ lg N = 7,85			10 minutes	-
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0,05 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,05 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/100= $70{,}00.10^4$ lg N/100 = 5,85			10 minutes	-
					6,17≤lg N/100 ≤ 6,70		lg Na	10 minutes	-
							lg R	10 minutes	-

Date of the test: March/29/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-6}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg No – lg Na)

UNVALID NEUTRALIZATION

BACILLUS CEREUS CIP 105.151 – Neutralizer 1

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST			
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 80% C	N			Final concentration of product % (V/V)		
					10^{-5}	10^{-6}		Contact time	80%	0,1%
Vc1-Vc2	Nvo 21 - 25 NvB 43 - 46	-	48 - 52	0 - 0	71 - 59	7 - 17	Vc1 - Vc2	10 minutes	-	-
$\bar{x}$	Nvo 23 NvB 45	-	50	0	$\bar{x}$ wm = $70,00.10^5$ lg N = 6,85			10 minutes	-	-
	$\bar{x}$ de Nvo et NvB entre 30 et 160	$\bar{x}$ de A ≥ 0,5 $\bar{x}$ de Nvo	$\bar{x}$ de B ≥ 0,5 $\bar{x}$ de NvB	$\bar{x}$ de C ≥ 0,5 $\bar{x}$ de Nvo	N/10= $70,00.10^4$ lg N/10 = 5,85			10 minutes	-	-
					6,17≤lg N/10 ≤ 6,70		lg Na	10 minutes	-	-
							lg R	10 minutes	-	-

Date of the test: March/29/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-5}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

UNVALID NEUTRALIZATION

BACILLUS CEREUS CIP 105.151 - Neutralizer 2

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST		
	Validation suspension **Nvo** **NvB**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 97% **C**	N			Final concentration of product % (V/V)	
					10^{-6}	10^{-7}		**Contact time**	**97%**
Vc1-Vc2	**Nvo** 21 - 25 **NvB** 43 - 46	-	47 - 55	0 - 0	71 - 59	7 - 17	Vc1 - Vc2	**10 minutes**	-
$\bar{x}$	**Nvo** 23 **NvB** 45	-	51	0	$\bar{x}$ wm = $70{,}00.10^6$ lg N = 7,85			**10 minutes**	-
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0,05 $\bar{x}$ of N_{VO}	$\bar{x}$ of B ≥ 0,05 $\bar{x}$ of N_{VB}	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of N_{VO}	N/100= $70{,}00.10^4$ lg N/100 = 5,85			**10 minutes**	-
					6,17≤lg N/100 ≤ 6,70		lg Na	**10 minutes**	-
							lg R	**10 minutes**	-

Date of the test: April/01/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-6}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 - lg Na)

UNVALID NEUTRALIZATION

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BACILLUS CEREUS CIP 105.151 – Neutralizer 2

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST			
	Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 80% C	N			Final concentration of product % (V/V)		
					10^{-5}	10^{-6}		Contact time	80%	0,1%
Vc1-Vc2	Nvo 21 - 25 NvB 43 - 46	-	47 - 55	17 - 20	71 - 59	7 - 17	Vc1 - Vc2	10 minutes	-	-
$\bar{x}$	Nvo 23 NvB 45	-	51	19	$\bar{x}$ wm = $70,00.10^5$ lg N = 6,85			10 minutes	-	-
	$\bar{x}$ de Nvo et NvB entre 30 et 160	$\bar{x}$ de A ≥ 0,5 $\bar{x}$ de Nvo	$\bar{x}$ de B ≥ 0,5 $\bar{x}$ de NvB	$\bar{x}$ de C ≥ 0,5 $\bar{x}$ de Nvo	N/100= $70,00.10^4$ lg N/10 = 5,85			10 minutes	-	-
					6,17≤lg N/10 ≤ 6,70		lg Na	10 minutes	-	-
							lg R	10 minutes	-	-

Date of the test: April/01/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-5}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

UNVALID NEUTRALIZATION

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BACILLUS CEREUS CIP 105.151 - Membrane filtration

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST		
	Validation suspension Nvo	Experimental conditions control A	Filtration control B	Method validation Product conc. 97% C	N			Final concentration of product % (V/V)	
					10^{-6}	10^{-7}		Contact time	97%
Vc1-Vc2	Nvo 57 - 63	34 - 34	46 - 50	28 - 40	182 - 188	17 - 21	Vc1 - Vc2	10 minutes	10^{0} 0 - 2 10^{-1} 0 - 0
$\bar{x}$	Nvo 60	34	48	34	$\bar{x}$ wm = $185,45.10^{6}$ lg N = 8,27			10 minutes	< 14
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0,05 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,05 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/100= $185,45.10^{4}$ lg N/100 = 6,27			10 minutes	< 140
					6,17≤lg N/100 ≤ 6,70		lg Na	10 minutes	< 2,15
							lg R	10 minutes	> 4,12

Date of the test: May/04/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-6}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg No - lg Na)

BACILLUS CEREUS CIP 105.151 – Membrane filtration

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST			
	Validation suspension Nvo	Experimental conditions control A	Filtration control B	Method validation Product conc. 80% C	N			Final concentration of product % (V/V)		
					10^{-5}	10^{-6}		Contact time	80%	0,1%
Vc1-Vc2	Nvo 57 - 63	36 - 44	46 - 50	25 - 35	182 - 188	17 - 21	Vc1 - Vc2	10 minutes	10^{0} 0 - 0 10^{-1} 0 - 0	10^{0} >330->330 10^{-1} >330->330
$\bar{x}$	Nvo 60	40	48	30	$\bar{x}$ wm = $185,45.10^{5}$ lg N = 7,27			10 minutes	< 14	>3300
	$\bar{x}$ de Nvo et NvB entre 30 et 160	$\bar{x}$ de A ≥ 0,5 $\bar{x}$ de Nvo	$\bar{x}$ de B ≥ 0,5 $\bar{x}$ de NvB	$\bar{x}$ de C ≥ 0,5 $\bar{x}$ de Nvo	N/100= $185,45.10^{4}$ lg N/10 = 6,27			10 minutes	< 140	> $3,3.10^{4}$
					6,17≤lg N/10 ≤ 6,70		lg Na	10 minutes	< 2,15	> 4,52
							lg R	10 minutes	> 4,12	< 1,75

Date of the test: May/04/2021

Vc = Count per ml (1 or 2 plates for $N/10^{-5}$)

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

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na

VI - CONCLUSION

According to the standard NF EN 17126 (December 2018), the product **F010474V1** (batch 7238), diluted in water for injectable preparations, the sporicidal concentration for medical devices disinfection determined under obligatory conditions, after a 10 minutes contact time at 20°C under clean conditions (0,3 g/L bovine albumin), against *Bacillus subtilis* CIP 52.62 and *Bacillus cereus* CIP 105.151, is **80%** (V/V).

The results hold only for the product under assay and apply to the sample as received.

F.V. - EN 17126 - 09.21 - EN

TEST REPORT

DETERMINATION OF THE SPORICIDAL ACTIVITY OF THE F010474V1 PRODUCT ACCORDING TO THE EN 17126 STANDARD

Delivered to: **Ms CHAKCHOUK**

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

Date of request: 06/14/2022

Study references: #155D61-2022-04

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 F010474V1 product against the strain *Clostridium difficile*.

This test report includes 7 pages.

Study completion date: 09/28/2022

Stephanie MOROT - BIZOT
PhD in Microbiology
Study Director

SUMMARY

Editor	Supervisor
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
3, RUE DE LA TERRE ROUGE
Espace industriel de Beaupré
25 220 ROCHE LEZ BEAUPRE
FRANCE

2 PRODUCT IDENTITY

Reference	Batch N°
F010474V1	7729

Expiration date: non communicated

Manufacturer: FRANKLAB

Date of manufacture: non communicated

Storage conditions: room temperature and darkness

Active substances: peracetic acid

Appearance of the product: clear.

Product diluent recommended by the manufacturer for use: none, ready-to-use product.

Date of delivery of the product: 06/29/2022

Date of tests: 06/29/2022 to 07/12/2022

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 100% (final concentration 80%)

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 5 min – 10 min – 15 min

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

Diluent used for the assays: distilled water

Diluent used for the bacterial suspensions: sterile trypton salt solution

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

Media and growth conditions: TSA (Trypton Soy Agar) – 37°C

Organic soil load: clean conditions, BSA 0,3 g/L

Product stability: limpid solution with organic soil load

Stop solution: sodium thiosulfate (2%), polysorbate 80 (10 g/L), with egg yolk (3 g/L)

Editor	Supervisor
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

4 CONCLUSIONS

According to the EN 17126 standard (December 2018), the F010474V1 product:

- **Demonstrated a sporicidal activity on the reference strain *Clostridium difficile*, when used at the concentration of 80.0%, for 10 min of contact time, at 20°C, in clean conditions (0,3 g/L bovine albumin)**

5 VALIDATIONS AND RESULTS SHEETS

Attached below.

- *Clostridium difficile*, **R = 4,13** from the concentration 80.0%

For all result sheets:

Methodology:
- 30 UFC/ml < Nv0 < 160 UFC/ml
- $1,5.10^7$ UFC/ml < N < 5.10^7 UFC/ml
- $6,17 \leq \lg N0 \leq 6,70$
- A ≥ 0,5 x Nv0
- B ≥ 0,5 x Nv0
- C ≥ 0,5 x Nv0

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 N0 – log Na)
VC = value counted per Petri dish

Editor	**Supervisor**
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director

6 RESULTS SHEET- TRIAL

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
Clostridium difficile	104	99	97	98	92	95	89	86
	$\bar{x}$	**101,5**	$\bar{x}$	**97,5**	$\bar{x}$	**93,5**	$\bar{x}$	**87,5**
	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		5 min	TRIAL		10 min	TRIAL		15 min
Clostridium difficile	1.10^{-5}	259	266	Vc			Vc			Vc		
	1.10^{-6}	27	29	1.10^{0}	76	63	1.10^{0}	20	23	1.10^{0}	15	9
	N	$2,64.10^{7}$		1.10^{-1}	9	8	1.10^{-1}	2	3	1.10^{-1}	1	1
	Log N0	**6,42**		Na	695,00		Na	215,00		Na	120,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			log Na	2,84		log Na	2,33		Log Na	2,08	
	× yes □ no			Lg R = logN0-logNa		**3,58**	Lg R = logN0-logNa		**4,09**	Lg R = logN0-logNa		**4,34**

Editor	Supervisor
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

7 RESULTS SHEET – REPETITION

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
Clostridium difficile	78	85	84	80	82	86	75	71
	$\bar{x}$	**81,5**	$\bar{x}$	**82,0**	$\bar{x}$	**84,0**	$\bar{x}$	**73,0**
	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		5 min	TRIAL		10 min	TRIAL		15 min
Clostridium difficile	1.10^{-5}	276	270	Vc			Vc			Vc		
	1.10^{-6}	32	29	1.10^{0}	99	82	1.10^{0}	22	16	1.10^{0}	10	11
	N	$2,76.10^{7}$		1.10^{-1}	10	11	1.10^{-1}	2	2	1.10^{-1}	1	1
	Log N0	**6,44**		Na	905,00		Na	190,00		Na	105,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			Log Na	2,96		Log Na	2,28		Log Na	2,02	
	× yes □ no			Lg R = logN0-logNa		**3,48**	Lg R = logN0-logNa		**4,16**	Lg R = logN0-logNa		**4,42**

Editor	Supervisor
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

8 TECHNICAL APPENDIX

Media:

TSA (Trypton Soy Agar), Dominique Dutscher, ref. 777410, batch 707171

ORGANIC SOIL LOAD:

Bovine serum albumin powder, Dominique Dutscher, Ref. 05479, batch STBB7838V

Diluent

Trypton-Sel Solution (TS)

Ingredients in grams per litre of distilled water:

- Trypton, Dominique Dutscher, ref. 1612, batch n ° 091229----------1,00 g/l
- Sodium chloride, Dominique Dutscher, ref. n° 19032391, batch n° 808211----------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---------- 10 g/L
- Sodium thiosulfate, SIGMA ALDRICH, ref. 72049, batch n° BCBD0584V --- 20 g/L
- Egg yolk, ---------- 3 g/L

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

Editor	Supervisor
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

MATERIAL COMPATIBILITY

Adaptation of the simple immersion test method described in standard NF S 94-402

- **Materials compatible with PERALEX 9 Hecto + :**
  - ✓ Stainless steel
  - ✓ Silicone
  - ✓ Endoscope sheath*
  - ✓ PVC
  - ✓ Anodized aluminium
  - ✓ HDPE
  - ✓ Reusable long cuff nitrile glove
  - ✓ Corian
  - ✓ Chrome

- **Materials not compatible with PERALEX 9 Hecto + :**
  - ✓ Brass
  - ✓ Copper
  - ✓ Raw aluminium

* Tests carried out on the brand's endoscopes FUJINON®

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contact@sterifrance.com

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STUDY REPORT

PERALEX 9 *Hecto +*

CORROSION TESTS

MAF078.2 - Adaptation of the simple immersion test method described in standard NF S 94-402

- **Laboratory that performed the tests:** ..... Chemistry laboratory – Franklab Company
- **Reference of the tests :** E2633
- **Person in charge of the tests :** ..... Catarina RODRIGUES

SAMPLE IDENTIFICATION

- **Product name:** ..... **PERALEX 9 Hecto +**
- **Manufacturer:** ..... FRANKLAB
- **Batch numbers / Manufacturing dates:** 4494 (21/11/2013)
- **Product characteristics:** ..... Clear liquid
- **Laboratory storage condition:** ..... in a PE can, at room temperature and protected from light

EXPERIMENTAL CONDITIONS

- **Control solution:** ..... mains water (Th = 445 mg/L CaCO3)
- **Test solution concentration:** 100%
- **pH of the test solution:** ..... 2,19 (pure)
- **Immersion time:** ..... 15 minutes
- **Number of immersions:** 50
- **Test temperature:** ..... Room temperature (20 ± 5°C)
- **Volume of the solutions:** ..... 200 ml

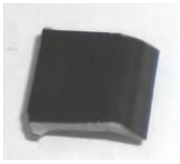
CHARACTERISTICS OF THE TESTED MATERIALS

Types of materials used:

A. Corian (Pieces of approximately 1.5 x 1.5 cm)

Characteristics of the surface condition of the materials:

Table 1 – List of alterations observed before immersion

Material reference	Alterations observed on the samples					
	1	2	3	4	5	6
A	 Smooth surface	 Smooth surface	 Smooth surface	 Smooth surface	 Smooth surface	 Smooth surface

TESTS RESULTS

Table 2 – List of alterations observed after 50 immersions of 15 minutes, regardless of their origin

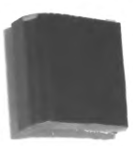
Material reference	Immersion cycle	Observed alterations					
		Batch 4494			Water		
		1	2	3	4	5	6
A	I-1	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface
	I-10	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface
	I-20	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface
	I-30	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface
	I-40	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface	Smooth surface
	I-50	 Smooth surface	 Smooth surface	 Smooth surface	 Smooth surface	 Smooth surface	 Smooth surface

Table 3 – List of observed alterations resulting only from immersion tests

Material reference	Immersion cycle	Observed alterations					
		Batch 4494			Water		
		1	2	3	4	5	6
A	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None

CONCLUSION

According to the test conditions, **PERALEX 9 Hecto +** is **non-corrosive** to Corian after 50 immersions of 15 minutes at room temperature

Date : 12/01/2016

SIGNATURE :

Catarina RODRIGUES

STUDY REPORT

Franklab
notre expertise l'Ultra-Propreté

PERALEX 9 *Hecto +*

CORROSIVE ACTION OF A DISINFECTANT

MAF078.2 – Adaptation of the single immersion test method described in standard NF S 94-402

- **Laboratory that performed the tests:** ..... Chemistry laboratory – **Franklab Company**
- **Reference of the tests:** E2633
- **Person in charge of the tests:** ..... Catarina RODRIGUES

SAMPLE IDENTIFICATION

- **Product name:** ..... **PERALEX 9 Hecto +**
- **Manufacturer:** ..... **Franklab**
- **Batch number / Manufacturing date:** 4494 (21/11/2013)
- **Product characteristics:** ..... Color: transparent
- **Manufacturer's recommended concentration:** Pure
- **Laboratory storage condition:** ..... in its original packaging, protected from light, at room temperature

EXPERIMENTAL CONDITIONS

- **Control solution:** ..... mains water (Th = 445 mg/L Ca CO_3)
- **Test solution concentration:** ..... pure
- **pH of the test solution:** 2,2
- **Immersion time:** ..... 15 minutes
- **Number of immersions:** 50
- **Test temperature:** ..... 20°C ± 5°C
- **Volume of the solutions:** ..... 200 ml

CHARACTERISTICS OF THE TESTED MATERIALS

Types of materials used:

A. FUJINON endoscope sheath (approximately 11 cm pieces)

Characteristics of the surface condition of the materials:

Table 1 – List of alterations observed on the materials before immersion

Material reference	Observed alterations					
	1	2	3	4	5	6
A						
	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches

TESTS RESULTS

Table 2 – List of alterations observed on the materials after 50 immersions of 15 minutes, regardless of their origin

Material reference	Immersion cycle	Observed alterations					
		1	2	3	4	5	6
A	I-1	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches
	I-10	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches
	I-20	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches
	I-30	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches
	I-40	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches	Smooth surface with scratches

Material reference	Immersion cycle	Observed alterations					
		1	2	3	4	5	6
	I-50	 Smooth surface with scratches	 Smooth surface with scratches	 Smooth surface with scratches	 Smooth surface with scratches	 Smooth surface with scratches	 Smooth surface with scratches

Table 3 – List of alterations observed on the materials, resulting only from the immersion tests

Material reference	Immersion cycle	Observed alterations					
		1	2	3	4	5	6
A	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None

CONCLUSION

Based on the test conditions, **PERALEX 9 Hecto +** is **non-corrosive** to the following materials:

A. FUJINON endoscope sheath

Date : 09/04/2015

SIGNATURE :

Catarina RODRIGUES

Ana Rodrigues

STUDY REPORT

Franklab
notre expertise l'Ultra-Propreté

PERALEX 9 *Hecto +*

CORROSIVE ACTION OF A DISINFECTANT

MAF078.2 - Adaptation of the single immersion test method described in standard NF S 94-402

- **Laboratory that performed the tests:** ..... Chemistry Laboratory– **Franklab Company**
- **Reference of the tests:** E2633
- **Person in charge of the tests:** ..... Catarina RODRIGUES

SAMPLE IDENTIFICATION

- **Product name:** ..... **PERALEX 9 Hecto +**
- **Manufacturer:** ..... **Franklab**
- **Batch number / Manufacturing date:** 4494 (21/11/2013)
- **Product characteristics:** ..... Color: Transparent
- **Manufacturer's recommended concentration:** Pure
- **Laboratory storage condition :** ..... in a black PE can, at room temperature

EXPERIMENTAL CONDITIONS

- **Control solution:** ..... mains water (Th = 445 mg/L Ca CO_3)
- **Test solution concentration:** ..... pure
- **pH of the test solution:** 2,2
- **Immersion time:** ..... 15 minutes
- **Number of immersions:** 50
- **Test temperature:** ..... 20°C ± 5°C
- **Volume of the solutions:** ..... 200 ml

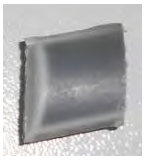
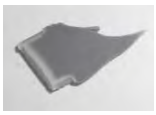
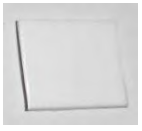
CHARACTERISTICS OF THE TESTED MATERIALS

Types of materials used:

A. Stainless steel (approximately 1.5 cm pieces)
B. PVC (Pieces of 1.5 x 1.5 cm approximately)
C. HDPE (pieces of 1.5 x 1.5 cm approximately)
D. Reusable nitrile glove with long cuff (ref.: Integra-300 G-360)

Characteristics of the surface condition of the materials:

Table 1 – List of alterations observed on the materials before immersion

Material reference	Observed alterations					
	1	2	3	4	5	6
A	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks
B	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface
C	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface
D	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface
	 Dry sawdust					

TEST RESULTS

Table 2 – List of alterations observed on the materials after 50 immersions of 15 minutes, regardless of their origin

Material reference	Immersion cycle	Observed alterations					
		Batch 4494			Water		
		1	2	3	4	5	6
A	I-1	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-10	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-20	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-30	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-40	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-50	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks
B	I-1	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-10	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-20	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-30	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-40	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-50	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface
C	I-1	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface

Material reference	Immersion cycle	Observed alterations					
		Batch 4494			Water		
		1	2	3	4	5	6
	I-10	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-20	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-30	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-40	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
	I-50	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface
D	I-1	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
		Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust
	I-10	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
		Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust
	I-20	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
		Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust
	I-30	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
		Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust
	I-40	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface	Rough surface
		Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust
	I-50	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface	 Rough surface
		Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust	Dry sawdust

Table 3 – List of alterations observed on the materials, resulting only from the immersion tests

Material reference	Immersion cycle	Observed alterations					
		Batch 4494			Water		
		1	2	3	4	5	6
A	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None
B	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None
C	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None
D	I-1	None	None	None	None	None	None
		None	None	None	None	None	None
	I-10	None	None	None	None	None	None
		None	None	None	None	None	None
	I-20	None	None	None	None	None	None
		None	None	None	None	None	None
	I-30	None	None	None	None	None	None
		None	None	None	None	None	None
	I-40	None	None	None	None	None	None
		None	None	None	None	None	None
	I-50	None	None	None	None	None	None
		None	None	None	None	None	None

CONCLUSION

According to the test conditions, **PERALEX 9 Hecto +** is **non-corrosive** to the following materials:

A. Stainless steel
B. PVC
C. HDPE

According to the test conditions, **PERALEX 9 Hecto +** does **not alter**:

D. Reusable nitrile glove with long cuff (ref. : Integra-300 G-360)

Date : 09/04/2015

SIGNATURE :

Catarina RODRIGUES

Ana Rodrigues

PERALEX 9 Hecto +

CORROSION TESTS

MAF078.1 - Adaptation of the simple immersion test method described in standard NF S 94-402

- **Laboratory that performed the tests:** ..... Chemistry laboratory – Franklab Company
- **Reference of the tests:** E2633
- **Person in charge of the tests:** ..... Viviana PEREIRA

SAMPLE IDENTIFICATION

- **Product name:** ..... **PERALEX 9 Hecto +**
- **Manufacturer:** ..... **FRANKLAB**
- **Batch number / Manufacturing dates:** ..... 5210 – 21/01/2016
- **Product characteristics:** ..... Clear liquid
- **Laboratory storage condition:** ..... in a PE can, at room temperature

EXPERIMENTAL CONDITIONS

- **Control solution:** ..... mains water (Th = 445 mg/L CaCO3)
- **Test solution concentration:** ..... pure
- **pH of the test solutions:** 2,30
- **Immersion time:** ..... 15 minutes
- **Number of immersions:** 50
- **Test temperature:** ..... Room temperature (20 ± 5°C)
- **Volume of the solutions:** ..... 200 ml

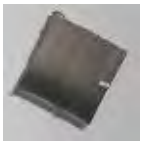
CHARACTERISTICS OF THE TESTED MATERIALS

Types of materials used:

A. Anodized aluminum (Pieces of approximately 2.5 x 2.5 x 1.5 cm)
B. Brass (Pieces of approximately 2 cm)
C. Copper (pieces of 1.5 x 1.5 cm)
D. Chrome (Pieces of approximately 2 x 1.5 cm)
E. Silicone (Pieces of approximately 3 x 1 cm)

Characteristics of the surface condition of the materials:

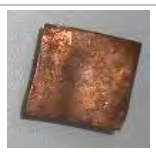
Table 1 – List of alterations observed on the materials before immersion

Material reference	Alterations observed on the samples					
	1	2	3	4	5	6
A	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends
B	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks
C	 Rough surface with scratches	 Rough surface with scratches	 Rough surface with scratches	 Rough surface with scratches	 Rough surface with scratches	 Rough surface with scratches
D	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting
E	 Uneven surface	 Uneven surface	 Uneven surface	 Uneven surface	 Uneven surface	 Uneven surface

TEST RESULTS

Table 2 – List of alterations observed after 50 immersions of 15 minutes, regardless of their origin

Material reference	Immersion cycle	Alterations observed on the samples in : PERALEX 9 Hecto + and in water; 50 immersions of 15 minutes					
		Batch 5210			Water		
		1	2	3	4	5	6
A	I-1	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends
	I-10	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends
	I-20	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends
	I-30	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends
	I-40	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends	Smooth surface and fragments at the ends
	I-50	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends	 Smooth surface and fragments at the ends
B	I-1	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-10	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-20	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-30	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-40	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Pitted surface with some cracks	Pitted surface with some cracks	Pitted surface with some cracks
	I-50	 Oxidized surface / tarnishing	 Oxidized surface / tarnishing	 Oxidized surface / tarnishing	 Pitted surface with some cracks	 Pitted surface with some cracks	 Pitted surface with some cracks
C	I-1	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches
	I-10	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches

Material reference	Immersion cycle	Alterations observed on the samples in : PERALEX 9 Hecto + and in water; 50 immersions of 15 minutes					
		Batch 5210			Water		
		1	2	3	4	5	6
	I-20	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches
	I-30	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches
	I-40	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Rough surface with scratches	Rough surface with scratches	Rough surface with scratches
	I-50	 Oxidized surface / tarnishing	 Oxidized surface / tarnishing	 Oxidized surface / tarnishing	 Rough surface with scratches	 Rough surface with scratches	 Rough surface with scratches
D	I-1	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting
	I-10	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting
	I-20	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting
	I-30	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting
	I-40	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting	Uneven surface with pitting
	I-50	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting	 Uneven surface with pitting
E	I-1	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface
	I-10	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface
	I-20	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface
	I-30	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface
	I-40	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface	Uneven surface

Material reference	Immersion cycle	Alterations observed on the samples in : PERALEX 9 Hecto + and in water; 50 immersions of 15 minutes					
		Batch 5210			Water		
		1	2	3	4	5	6
	I-50	 Uneven surface	 Uneven surface	 Uneven surface	 Uneven surface	 Uneven surface	 Uneven surface

Table 3 – List of observed alterations resulting only from immersion tests

Material reference	Immersion cycle	Alterations observed on the samples in : PERALEX 9 Hecto + and in water; 50 immersions of 15 minutes					
		Batch 5210			Water		
		1	2	3	4	5	6
A	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None
B	I-1	None	None	None	None	None	None
	I-10	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-20	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-30	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-40	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-50	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
C	I-1	None	None	None	None	None	None
	I-10	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-20	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-30	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-40	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
	I-50	Oxidized surface / tarnishing	Oxidized surface / tarnishing	Oxidized surface / tarnishing	None	None	None
D	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None

Material reference	Immersion cycle	Alterations observed on the samples in : PERALEX 9 Hecto + and in water; 50 immersions of 15 minutes					
		Batch 5210			Water		
		1	2	3	4	5	6
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None
E	I-1	None	None	None	None	None	None
	I-10	None	None	None	None	None	None
	I-20	None	None	None	None	None	None
	I-30	None	None	None	None	None	None
	I-40	None	None	None	None	None	None
	I-50	None	None	None	None	None	None

CONCLUSION

According to the test conditions, **PERALEX 9 Hecto +** is **non-corrosive** to the following materials after 50 15-minute immersions at room temperature:

A. Anodized aluminum
D. Chrome
E. Silicone

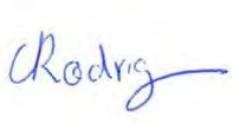
According to the test conditions, **PERALEX 9 Hecto +** is **corrosive** to the following materials after 50 15-minute immersions at room temperature:

B. Brass
C. Copper

Important note: PERALEX 9 Hecto+ is not corrosive on anodized aluminum, but due to its chemical components, PERALEX 9 Hecto+ is corrosive on pure aluminum.

Date : 29/03/2016

SIGNATURE :
Catarina RODRIGUES



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notre expertise l'Ultra-Propreté

STABILITY AND STORAGE CONDITIONS PERALEX 9 HECTO +

- **Pure product :**
  - **Storage:** between +5°C and +25°C.

  Stability :
  - **Unopened can:** 1 year from date of manufacture indicated on the can.
  - **Opened can:** 1 month from the date of opening the can.
  - **Stability of disinfection bath:** 7 days*

* Study report (STAB_Bath_474) included in the scientific file available on request

STUDY REPORT

Franklab
notre expertise l'Ultra-Propreté

PERALEX 9 *Hecto +*

EVALUATION OF THE USEFUL LIFE OF PERACETIC ACID DISINFECTANT BATHS

NFT 72-901 December 2008

PRINCIPLE OF THE STUDY

The objective of this protocol is to evaluate the useful life of manual disinfection baths by simulating the specific conditions of use of the product under evaluation. The tests performed include :

- Physico-chemical dosages of peracetic acid (APA), (possibly hydrogen peroxide (H_2O_2) and pH measurements)
- Microbiological efficacy tests (see report n°15-06).

IDENTIFICATION OF THE SAMPLE

- **Name of product:** ..... PERALEX 9 Hecto +
- **Batch number:** 4494
- **Manufacturer:** ..... FRANKLAB
- **Production date:** 21/11/2013
- **Aspect of the product:** ..... Colorless liquid, acetic acid odor
- **Date received at the laboratory(ies):** ..... unspecified
- **Storage conditions:** ..... protected from light and heat
- **Duration of bath use:** ..... 7 days
- **Method of bath preparation:** ..... Pour the contents of the can into a container. Ready to use bath
- **Critical concentration:** ..... between 700 and 1200ppm of APA
- **Period of analysis:** ..... from 31/03/2015 to 08/04/2015
- **Diluent of the product recommended by the manufacturer:** ..... None (product used pure)

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S.A.S. au capital de 1 000 000 € - RCS Versailles 76 B 635 - SIRET 306 563 206 00052 - APE 2041Z - TVA FR38306563

ORGANIZATION OF THE TEST

- **Type of container:** ..... 2 PP container
- **Volume treated:** 10L
- **Duration of the stability study:** ..... 7 days
- **Type of hood:** ..... chemical hood

PHYSICO-CHEMICAL TESTS

IDENTIFICATION WHICH PERFORMED PHYSICO-CHEMICAL TESTS

Chemical Laboratory FRANKLAB company

RESULTS OF PHYSICO-CHEMICAL TESTS

Step 1:

Method: Take a dosage of peracetic acid (APA) and possibly hydrogen peroxide according to validated methods. Measure the pH.

Compare the dosage results and pH with the product indications.

Result :

Criteria	Specifications of the PERALEX 9 Hecto+	Results	Compliance with specifications
pH	2.50 +/-0.50	2.33	**COMPLIANT**
Title in H_2O_2	7.90 +/-0.50	7.92	**COMPLIANT**
Title in APA	700 <=x <=1200ppm	860	**COMPLIANT**

Conclusion:

The measured contents of APA and hydrogen peroxide and the pH correspond to the product indications, the second step can be implemented.

Step 2:

Method: - A protein addition at D0 and a daily addition except on weekends for products of use >= 5 days.

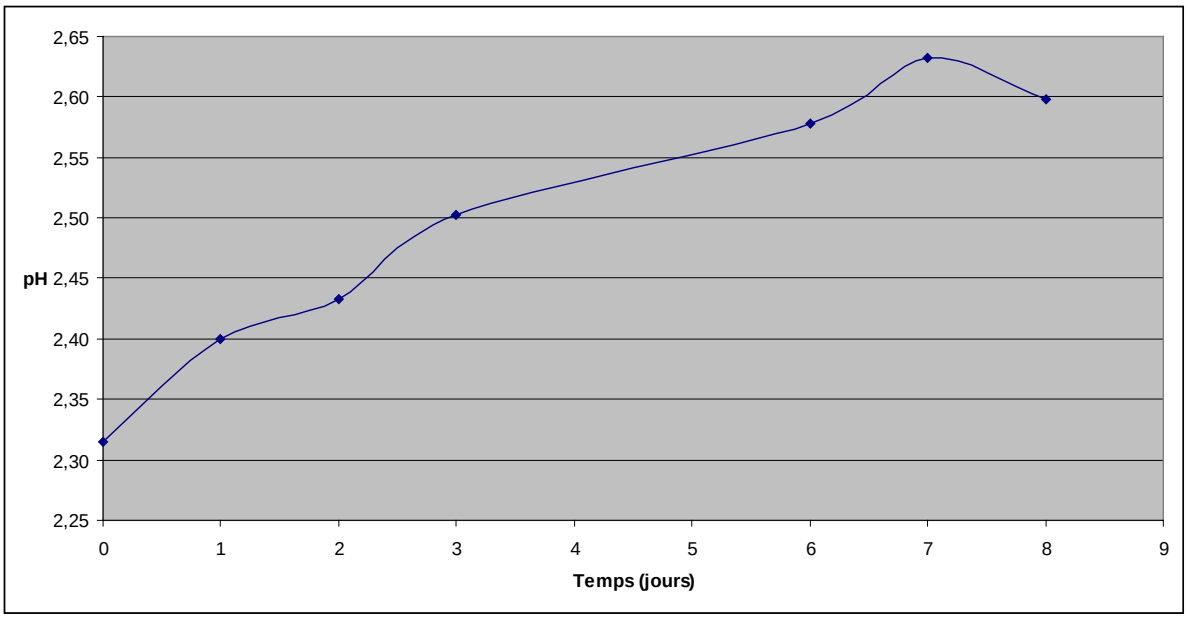
- an opening of the containers lasting 1 hour on D0 and a daily opening of the containers lasting 1 hour, except on weekends for products >= 5 days.

- Physico-chemical analyses are carried out at all times

Day	Addition of BSA (70ml)	Opening of the container : 1h	Sample collection
D0	X	X	X
D1	X	X	X
D2	X	X	X
D3	X	X	X
D4			
D5			
D6	X	X	X
D7	X	X	X
D8	X	X	X

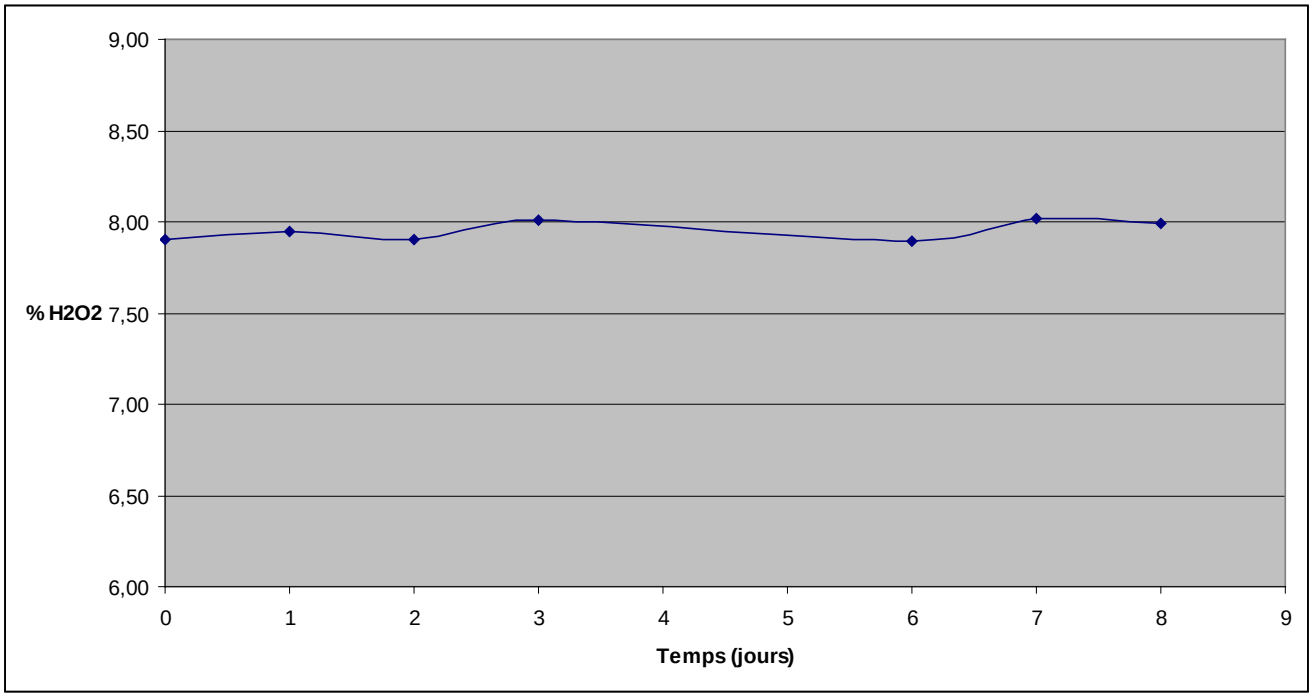
Results: *pH evolution over time (specification: 2.50 +/-0.50)*

	Container 1		Container 2		Average	Compliance with specifications
Sample collection	1st measure	2nd mesure	1st measure	2nd mesure		
D0	2,32	2,41	2,22	2,31	**2,32**	**COMPLIANT**
D1	2,41	2,46	2,35	2,38	**2,40**	**COMPLIANT**
D2	2,46	2,48	2,38	2,41	**2,43**	**COMPLIANT**
D3	2,53	2,52	2,47	2,49	**2,50**	**COMPLIANT**
D6	2,55	2,55	2,61	2,60	**2,58**	**COMPLIANT**
D7	2,61	2,62	2,65	2,65	**2,63**	**COMPLIANT**
D8	2,61	2,62	2,58	2,58	**2,60**	**COMPLIANT**



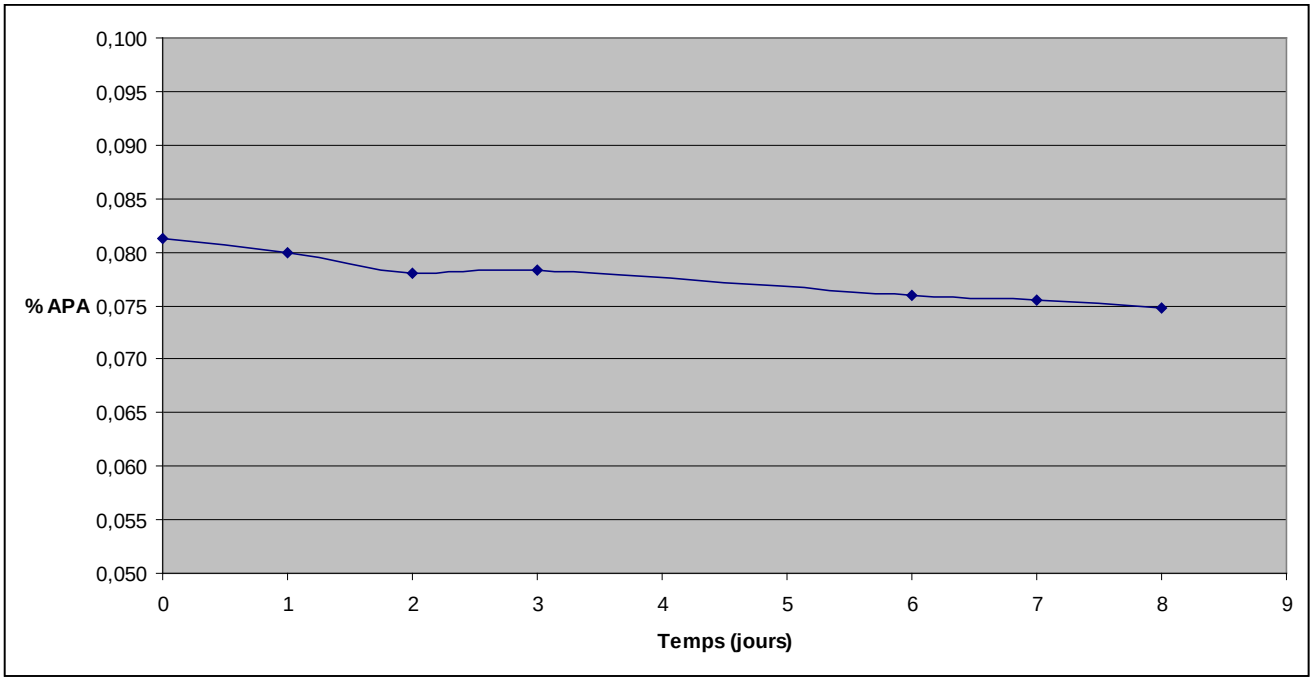
Results: *Evolution of H2O2 content (in %) over time (specification : 7.90 +/-0.50)*

	Container 1		Container 2		Average	Compliance with specifications
Sample collection	1st measure	2nd measure	1st measure	2nd measure		
D0	7,90	7,90	7,96	7,83	**7,90**	**COMPLIANT**
D1	7,86	7,95	8,02	7,98	**7,95**	**COMPLIANT**
D2	7,87	7,94	7,87	7,93	**7,90**	**COMPLIANT**
D3	7,74	7,95	8,31	8,04	**8,01**	**COMPLIANT**
D6	7,88	7,98	7,77	7,94	**7,89**	**COMPLIANT**
D7	8,08	7,91	8,03	8,05	**8,02**	**COMPLIANT**
D8	7,93	7,99	8,02	8,01	**7,99**	**COMPLIANT**



Results : *Evolution of the APA content by titrimetry (in %) over time (specification : 0,070 <=x <=0,120)*

Sample collection	Container 1		Container 2		Average	Compliance with specifications
	1st measure	2nd measure	1st measure	2nd measure		
D0	0,081	0,082	0,080	0,082	**0,081**	**COMPLIANT**
D1	0,078	0,082	0,080	0,080	**0,080**	**COMPLIANT**
D2	0,077	0,077	0,079	0,079	**0,078**	**COMPLIANT**
D3	0,077	0,079	0,080	0,077	**0,078**	**COMPLIANT**
D6	0,075	0,076	0,076	0,077	**0,076**	**COMPLIANT**
D7	0,074	0,077	0,075	0,076	**0,076**	**COMPLIANT**
D8	0,073	0,076	0,075	0,075	**0,075**	**COMPLIANT**



CONCLUSION OF THE PHYSICO-CHEMICAL TESTS

According to this protocol of daily contamination of the bath of PERALEX 9 Hecto+ (batch 4494) by addition of BSA, the physico-chemical analyses carried out show that:

- the pH value increases slightly throughout the duration of the tests **but remains within the limits of the initially defined specifications**
- the H202 rate remains relatively stable throughout the duration of the tests and **within the limits of the initially defined specifications**
- the APA rate decreases slightly throughout the duration of the tests but **remains within the limits of the initially defined specifications**

MICROBIOLOGICAL TESTS

IDENTIFICATION WHICH PERFORMED THE PHYSICO-CHEMICAL TESTS

Hospital Hygiene Laboratory, CHU of Clermont-Ferrand

RESULTS OF MICROBIOLOGICAL TESTS

Method: *The m*icrobiological tests include:

- the application of standard NF EN 1040 under the mandatory conditions (two strains, contact time = 5min) on the bath solution considered as "products used without dilution".

- the application of standard NF EN 14348 on a single strain (*M. terrae*) in the absence of any interfering substance and with 15min of contact time or a time equal to the minimum soaking time indicated, on a bath solution considered as "products used without dilution".

Results :

Standard	Strains	Active Concentration	
		T0	Final T
EN 1040	*Staphylococcus aureus* CIP 4.83	8% 5min	8% 5min
	Pseudomonas aeruginosa CIP 103.467	2% 5min	8% 5min
EN 14347	*Mycobacterium terrae* CIP 104.321	80% 10min	80% 10min

Please refer to report n°15-06 for more detailed results (available on request).

CONCLUSION OF MICROBIOLOGICAL TESTS

The PERALEX 9 Hecto+ has demonstrated, under the conditions proposed for its use, an ability to maintain sufficient activity to justify its duration of use (7 days) under the following conditions :

- logarithmic reduction of at least 5 log according to EN 1040 on *P. aeruginosa* and *S. aureus* throughout the duration of the tests at 8% concentration in 5min contact time
- logarithmic reduction of at least 4 log according to EN 14348 on *M. terrae* throughout the duration of the tests at a concentration of 80% in 10min contact time

CONCLUSION

Tests			PERALEX 9 Hecto+ batch 4494 Useful life of the bath: 7 days	
	Criteria		T0	Final T
PHYSICO-CHEMICALS	**pH**		2,32	2,60
	H202 content		7,90	7,99
	APA content		0,081%	0,075%
MICROBIOLOGY	**EN 1040**	*Staphylococcus aureus* CIP 4.83	8% 5min	8% 5min
		Pseudomonas aeruginosa CIP 103.467	2% 5min	8% 5min
	EN 14348	*Mycobacterium terrae* CIP 104.321	80% 10min	80% 10min

The product **PERALEX 9 Hecto+** batch 4494 used for the manual disinfection of endoscope-type heat-sensitive medical devices complies with standard NF T 72-901 because it has demonstrated, under the conditions proposed for its use, an ability to maintain sufficient microbiological activity and physico-chemical stability during its 7 day period of use and under the following conditions:

- preparation of a ready-to-use bath

- for a duration of use of 7 days

Date : 14/09/2015

SIGNATURE :

Nadia CHAKCHOUK
Responsable du laboratoire de chimie

REPORT STANDARD NF T 72-901

Laboratory that performed the test

Hospital Hygiene Laboratory

Centre de Biologie 6éme étage,
CHU de Clermont-Ferrand
63003 CLERMONT-FERRAND

Client

FRANKLAB

BP 63
78185 Saint Quentin en Yvelines

Identification of the sample

Name of product: F010474V1
Manufacturer: Franklab
Diluent of the product recommended by the manufacturer: None (Product used pure)
Active substance(s): Peracetic acid
Batch number: 4494
Expiry date: Not specified
Analysis period: From 31/03/15 to 29/04/15
Duration of use of the baths: 7 days
Bath preparation methods: Pour the contents of the bottle into a ready-to-use bath container.
Storage conditions (temperature, etc.): in dark and at room temperature
Type of container used: 30L polypropylene container
Volume processed: 10 Litres
Appearance of product: Liquid, Colourless, Acetic odour

Day of sampling: D0

Dilution-neutralisation method:

Neutraliser used: Pancreatic digestion of casein 17g, Enzymatic digestion of soya 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30ml, Sodium Pyruvate 30g, Distilled water qsp. 1L.
Test temperature: 20°C
Test strain: *Staphylococcus aureus CIP 4.83*
Incubation temperature: 37°C
Test date: 31/03/15
Diluent used for the product test solutions: Sterile distilled water
Interfering substances: None
Appearance of product dilutions: colourless, liquid
Appearance of the product during the test: no precipitate

Validation and controls

Validation suspension (N_{vo})			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	206		V_{c1}	199		V_{c1}	216		V_{c1}	208	
V_{c2}	231	$\bar{x}$ =219	V_{c2}	199	$\bar{x}$ = 199	V_{c2}	201	$\bar{x}$ =209	V_{c2}	171	$\bar{x}$ =190
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ of $A \geq 0.5$ x $\bar{x}$ of N_{vo}?			$\bar{x}$ of $B \geq 0.5$ x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☐	No ☒		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N0)	N	V_{c1}	V_{c2}	$N = (119 + 102) / 2x10^{-7} = 9.05$ log $N_0 = N/10 = 8.05$ log N_0 is between 7.17 and 7.70
	10^{-6}	>660	>660	
	10^{-7}	119	102	

Yes	No
	X

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x}$ x 10	Log N_a	$log\ R$ (N_0 = 8.05)
8%	**5 minutes**	0	0	<140	<2.15	**>5.9**
2%	5 minutes	>660	600	>6300	>3.80	<4.25
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<4.23
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<4.23

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: Weighted averages were not checked because only one dilution was used for the calculation of N.

Notes about the results

- ✓ All controls give values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.
- ✓ The test (N) and validation (Nv) suspensions are beyond the limits noted in the standard; however, the visible reduction remains above 5 log.

Dilution-neutralisation method:

Neutraliser used: Pancreatic digest of casein 17g, Enzymatic digest of soybeans 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30ml, Sodium pyruvate 30g, Distilled water qsp. 1L

Test temperature: ..... 20°C

Test strain: ..... *Pseudomonas aeruginosa, CIP 103.467*

Incubation temperature: ..... 37°C

Test date: 31/3/15

Diluent used for the product test solutions: ..... Sterile distilled water

Interfering substances: ..... None

Appearance of product dilutions: ..... colourless, liquid

Appearance of the product during the test: ..... no precipitate

Validation and controls

Validation suspension (N_{vo})			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	92	$\bar{x}$ = 94	V_{c1}	64	$\bar{x}$ = 61	V_{c1}	59	$\bar{x}$ = 70	V_{c1}	69	$\bar{x}$ = 71
V_{c2}	95		V_{c2}	58		V_{c2}	80		V_{c2}	72	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ of *A* is $\geq 0.5 \times \bar{x}$ of N_{vo}?			$\bar{x}$ of *B* is $\geq 0.5 \times \bar{x}$ of N_{vo}?			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{vo}?		
Yes ☒ No ☐			Yes ☒ No☐			Yes ☒ No ☐			Yes ☒ No ☐		

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N0)	N	V_{c1}	V_{c2}	$N = (387 + 363 + 52 + 61) / 2.2 \times 10^{-6} = 8.59$ log $N_0 = N/10 = 7.59$ log N_0 is between 7.17 and 7.70	Yes	No
	10^{-6}	387	363		X	
	10^{-7}	52	61			

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	Log N_a	$\log R$ ($N_0 = 7.59$)
8%	**5 minutes**	0	0	<140	<2.15	**>5.44**
2%	**5 minutes**	0	0	<140	<2.15	**>5.44**
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<3.77
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<3.77

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: D= [(387 + 363) *12]* / [(52 + 61)/2] = 6.64
6.64 is between 5 and 15.

Remarks on the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.

Membrane filtration method:

Test temperature: ..... 20°C
Interfering substances: ..... None
Test strain: ..... *Mycobacterium terrae CIP 104.32.1.*
Incubation temperature: ..... 37°C
Test date: 31/3/15
Diluent used for the product test solutions: ..... Sterile distilled water
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate
Type of membranes: ..... Cellulose ester, 0.45µm, 47mm diameter
Reference: 11406-47-ACN

Validation and controls

Validation suspension (N_{v0})			Experimental conditions control (A)			Filtration control(B)			Method validation (C)		
V_{c1}	32	$\bar{x}$ = 30	V_{c1}	17	$\bar{x}$ = 16	Vol	17	$\bar{x}$ = 18	V_{c1}	16	$\bar{x}$ = 18
V_{c2}	28		V_{c2}	15		V_{c2}	18		V_{c2}	20	
$30 \leq \bar{x}$ of $N_{v0} \leq 160$?			$\bar{x}$ of A is $\geq 0.5 \times \bar{x}$ of N_{v0}?			$\bar{x}$ of B is $> 0.5 \times \bar{x}$ of N_{v0}?			$\bar{x}$ of C is $> 0.5 \times \bar{x}$ of N_{v0}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

Test suspension and Test

Test suspension (N and N0)	N	V_{c1}	V_{c2}	N = (434 + 434 + 56 + 58) / 2.2×10^{-7} = 9.65 log N_0 = N/10 = 8.65 log N_0 is between 8.17 and 8.70	Yes	No
	10^{-7}	434	434		X	
	10^{-8}	56	58			

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable.

Uncountable As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, the 80% concentrated product here.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 4 log.
- ✓ No precipitate formation during test.

Concentration/ Times	Degree of dilution	V_{c1}	V_{c2}	N_a	Log N_a	*log R* ($N_0 = 8.65$)
80% **10 minutes**	10^0	36*	44*	400	2.60	**6.05**
	10^{-1}	3	1			
	10^{-2}	0	0			
	10^{-3}	0	0			
40% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<2.43
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	>165*	>165*			
20% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<2.43
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	>165*	>165*			

Weighted averages control: D= [(434 + 434) /2 / [(56 + 58) /2] = 7.61
7.61 is between 5 and 15.

Day of sampling: D3

Dilution-neutralisation method:

Neutraliser used: Pancreatic digest of casein 17g, Enzymatic digest of soybeans 3g, Sodium chloride 5g, Dipotassium hydrogen, phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30ml, Sodium pyruvate 30g, Distilled water qsp. 1L

Test temperature: ..... 20°C
Test strain: ..... *Staphylococcus.aureus CIP 4.83*
Incubation temperature: ..... 37°C
Test date: 3/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Interfering substances: ..... None
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... No precipitate

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	183	$\bar{x}$ = 170	V_{c1}	163	$\bar{x}$ = 163	V_{c1}	175	$\bar{x}$ = 178	V_{c1}	168	$\bar{x}$ = 180
V_{c2}	157		V_{c2}	162		V_{c2}	181		V_{c2}	192	
30 ≤ $\bar{x}$ of N_{vo} ≤160?			$\bar{x}$ of *A* is ≥ 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of *B* is ≥ 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☐	No ☒		Yes	☒	No ☐	Yes ☒		No ☐	Yes ☒		No ☐

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N0)	N	V_{c1}	V_{c2}	N = (109 + 102) / 2x10^{-7} = 9.02 log N_0 = N/10 = 8.02 log N0 is between 7.17 and 7.70	Yes	No
	10^{-6}	>660	>660		X	
	10^{-7}	109	102			

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x}$ x 10	Log N_a	$\log R$ (N_0 = 8.02)
8%	**5 minutes**	0	0	<140	<2.15	**>5.87**
2%	5 minutes	>660	>660	>6600	>3.82	<4.20
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<4.20
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<4.20

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: Weighted averages were not checked because only one dilution was used for the calculation of N.

Notes about the results

- ✓ All controls give values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.
- ✓ The test (N) and validation (Nv) suspensions are beyond the limits noted in the standard; however, the visible reduction remains above 5 log.

Dilution-neutralisation method:

Neutraliser used:Pancreatic digestion of casein.17g, Enzymatic digestion of soya 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2,5g, Glucose 2,5g, Polysorbate 80 30 ml, Sodium pyruvate 30g, Distilled water qsp. 1L

Test temperature: ..... 20°C
Test strain: ..... *Pseudomonas aeruginosa CIP 103.467*
Incubation temperature: ..... 37°C
Test date: 3/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Interfering substances: ..... None
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	66	$\bar{x}$ = 71	V_{c1}	62	$\bar{x}$ = 53	V_{c1}	70	$\bar{x}$ = 67	V_{c1}	74	$\bar{x}$ = 67
V_{c2}	76		V_{c2}	44		V_{c2}	63		V_{c2}	68	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ of A is $\geq 0.5 \times \bar{x}$ of N_{vo}?			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of N_{vo}?			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No☐	

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N0)	N	V_{c1}	V_{c2}	$N = (290 + 292 + 33 + 39) / 2.2 \times 10^{-6} = 8.47$ log $N_0 = N/10 = 7.47$ log N_0 is between 7.17 and 7.70.	Yes	No
	10^{-6}	290	292		X	
	10^{-7}	33	39			

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	Log N_a	$Log\ R$ ($N_0 = 7.47$)
8%	**5 minutes**	1	0	<140	<2.15	**>5.32**
2%	**5 minutes**	22	20	210	2.32	**5.15**
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<3.65
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<3.65

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: D= [(290 + 292) /2] / [(33 + 39)/2] = 8.08
8.08 is between 5 and 15.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.

Membrane filtration method:

Test temperature: ..... 20°C
Interfering substances: ..... None
Test strain: ..... *Mycobacterium terrae CIP 104.321*
Incubation temperature: ..... 37°C
Test date: 3/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate
Type of membranes: ..... Cellulose ester 045µm, 47 mm diameter
Reference: 1.1406-47-ACN

Validation and controls

Validation suspension (N_{vo})			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{c1}	66	$\bar{x} = 71$	V_{c1}	52	$\bar{x} = 48$	V_{c1}	70	$\bar{x} = 67$	V_{c1}	74	$\bar{x} = 71$
V_{c2}	76		V_{c2}	44		V_{c2}	63		V_{c2}	68	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ of A is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of B is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

Test suspension and Test

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	$N = (240 + 355 + 32 + 23) / 2.2 \times 10^{-7} = 9.47$ log $N_0 = N/10 = 8.47$ log N0 is between 8.17 and 8.70	Yes	No
	10^{-7}	240	355		X	
	10^{-8}	32	23			

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable.

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, the 80% concentrated product here.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 4 log.
- ✓ No precipitate formation during test.

Concentration/ Times.	Degree of dilution	V_{c1}	V_{C2}	N_a	Log N_a	*log R* ($N_0 = 8.47$)
80% **10 minutes**	10^0	35*	70*	525	2.72	**5.74**
	10^{-1}	3	1			
	10^{-2}	0	0			
	10^{-3}	0	0			
40% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<2.24
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	Inc*	Inc*			
20% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<2.24
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	Inc*	Inc*			

Weighted averages control: D= [(240 + 355) /2] [(32 + 23) /2] = 10.8
10.8 is between 5 and 15.

Day of sampling: D7

Dilution-neutralisation method:

Neutraliser used: Pancreatic digest of casein 17g, Enzymatic digest of soybeans 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30ml, Sodium pyruvate 30g, Distilled water qsp. 1L

Test temperature: ..... 20°C

Test strain: ..... *Staphylococcus.aureus CIP 4.83*

Incubation temperature: ..... 37°C

Test date: 7/4/15

Diluent used for the product test solutions: ..... Sterile distilled water

Interfering substances: ..... None

Appearance of product dilutions: ..... colourless, liquid

Appearance of the product during the test: ..... no precipitate

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	98	$\bar{x}$ =101	V_{c1}	90	$\bar{x}$ = 78	V_{c1}	80	$\bar{x}$ = 86	V_{c1}	92	$\bar{x}$ = 87
V_{c2}	104		V_{c2}	66		V_{c2}	92		V_{c2}	82	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ *of A* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ *of B* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	$N = (301 + 299 + 26 + 33) / 2.2 \times 10^{-6} = 8.48$ log $N_0 = N/10 = 7.48$ log N0 is between 7.17 and 7.70	Yes	No
	10^{-6}	301	299		X	
	10^{-7}	26	33			

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	Log N_a	*log R* (N_0 = 7.48)
8%	**5 minutes**	0	0	<140	<2.15	**>5.33**
2%	5 minutes	Inc	Inc	>6600	>3.82	<3.66
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<3.66
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<3.66

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: D= [(301 + 299) /2] / [(26 + 33) /2] = 10.2
10.2 is between 5 and 15.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.

Dilution-neutralisation method:
Neutraliser used: Pancreatic digest of casein 17g, Enzymatic digest of soybeans 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30ml, Sodium pyruvate 30g, Distilled water qsp. 1L

Test temperature: ..... 20°C
Test strain: ..... *Pseudomonas aeruginosa CIP 103.467*
Incubation temperature: ..... 37°C
Test date: 7/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Interfering substances: ..... None
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	86	$\bar{x}$ =101	V_{c1}	77	$\bar{x}$ = 78	V_{c1}	103	$\bar{x}$ = 86	V_{c1}	89	$\bar{x}$ = 87
V_{c2}	93		V_{c2}	82		V_{c2}	97		V_{c2}	109	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ of A is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of B is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

Vc : Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	$N = (401 + 396 + 56 + 58) / 2.2 \times 10^{-6} = 8.62$ log $N_0 = N/10 = 7.62$ log N_0 is between 7.17 and 7.70.	Yes	No
	10^{-6}	401	396		X	
	10^{-7}	56	58			

Product conc.	Contact time	V_{c1}	V_{c2}	$Na = \bar{x} \times 10$	Log N_a	$Log\ R$ ($N_0 = 7.62$)
8%	**5 minutes**	0	0	<140	<2.15	**>5.47**
2%	**5 minutes**	207	203	2050	3.31	**4.31**
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<3.80
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<3.80

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: $D = [(401 + 396)/2] / [(56 + 58)/2] = 7$

7 is between 5 and 15.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.

Membrane filtration method:

Test temperature: ..... 20°C
Interfering substances: ..... None
Test strain: ..... *Mycobacterium terrae CIP 104.321*
Incubation temperature: ..... 37°C
Test date: 7/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate
Type of membranes: ..... Cellulose ester, 045µm, 47mm diameter
Reference: 11406-47:ACN

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	117	$\bar{x}$ =101	V_{c1}	103	$\bar{x}$ = 78	V_{c1}	118	$\bar{x}$ = 86	V_{c1}	99	$\bar{x}$ = 87
V_{c2}	103		V_{c2}	109		V_{c2}	125		V_{c2}	89	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ *of A* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ *of B* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

Test suspension and Test

Test suspension (N and N_o)	N	V_{c1}	V_{c2}	N = (456 + 399 + 46 + 38)/2.2 x 10^{-7} = 9.63 log N_0 = N/10 = 8.63 log N0 is between 8.17 and 8.70	Yes	No
	10^{-7}	456	399		X	
	10^{-8}	46	38			

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable.

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, the 80% concentrated product here.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 4 log.
- ✓ No precipitate formation during test.

Concentration/ Times.	Degree of dilution	V_{c1}	V_{c2}	N_a	Log N_a	*log R* (N_0 = 8.63)
80% **10 minutes**	10^0	72*	50*	610	2.79	**5.84**
	10^{-1}	1	4			
	10^{-2}	0	0			
	10^{-3}	0	0			
40% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<2.41
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	Inc*	Inc*			
20% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<2.41
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	Inc*	Inc*			

Weighted averages control: D= [(456 + 499) /2] / [(46 + 38) /2] = 11.4
11.4 is between 5 and 15.

Day of sampling: D8

Dilution-neutralisation method:

Reasons for choice of method: ..... Method recommended by the standard
Neutraliser used: Pancreatic digestion of casein 17g, Enzymatic digestion of soya 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2,5g, Polysorbate 80 30 ml, Sodium pyruvate 30g, Distilled water qsp. 1L
Test temperature: ..... 20°C
Test strain: ..... *Staphylococcus aureus CIP 4.83*
Incubation temperature: ..... 37°C
Test date: 8/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Interfering substances: ..... None
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	120	$\bar{x}$ =101	V_{c1}	130	$\bar{x}$ = 78	V_{c1}	133	$\bar{x}$ = 86	V_{c1}	123	$\bar{x}$ = 87
V_{c2}	103		V_{c2}	143		V_{c2}	136		V_{c2}	155	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ *of A* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ *of B* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; No: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N0)	N	V_{c1}	V_{c2}	N = (596 + 509 + 75 + 86) / 2.2 x 10^{-6} = 8.76 log N_0 = N/10 = 7.76 log N_0 is between 7.17 and 7.70.
	10^{-6}	596	509	
	10^{-7}	75	86	

Yes-	No
	X

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	Log N_a	$log\ R$ ($N_0 = 7.76$)
8%	**5 minutes**	0	0	<140	<2.15	**>5.61**
2%	5 minutes	Inc	Inc	>6600	>3.82	<3.94
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<3.94
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<3.94

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: D= [(596 + 509) /2] / [(75 + 86) /2] = 8.05
8.05 is between 5 and 15.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log. No precipitate formation during the test.
- ✓ The test suspension (N) is beyond the limits noted in the standard; however, the visible reduction remains above 5 log.

Dilution-neutralisation method:

Neutraliser used: pancreatic digestion of casein 17g, Enzymatic digestion of Soy 3g, Sodium chloride 5g, Dipotassium hydrogen phosphate 2.5g, Glucose 2.5g, Polysorbate 80 30ml, Sodium Pyruvate 30g, Distilled water qsp. 1L
Test temperature: ..... 20°C
Test strain: ..... *Pseudomonas aeruginosa CIP 103.467*
Incubation temperature: ..... 37°C
Test date: 8/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Interfering substances: ..... None
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	89	$\bar{x}$ =101	V_{c1}	72	$\bar{x}$ = 78	V_{c1}	93	$\bar{x}$ = 86	V_{c1}	96	$\bar{x}$ = 87
V_{c2}	94		V_{c2}	70		V_{c2}	88		V_{c2}	85	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ *of A* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ *of B* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{vo}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, i.e. 8% here.

Test suspension and Test

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	$N = (445 + 445 + 73 + 56) / 2.2x10^{-6} = 8.67$ log $N0 = N/10 = 7.67$ log N_0 is between 7.17 and 7.70.	Yes	No
	10^{-6}	445	445		X	
	10^{-7}	73	56			

Product conc.	Contact time	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	Log N_a	$Log\ R$ ($N_0 = 7.67$)
8%	**5 minutes**	0	0	<140	**<2.15**	**>5.52**
2%	**5 minutes**	0	0	<140	**<2.15**	**>5.52**
0.5%	5 minutes	Inc	Inc	>6600	>3.82	<3.85
0.125%	5 minutes	Inc	Inc	>6600	>3.82	<3.85

V_c: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable

Weighted averages control: $D = [(445 + 445)/2] / [(73 + 56)/2] = 6.9$
6.9 is between 5 and 15.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a logarithmic reduction of at least 5 log.
- ✓ No precipitate formation during test.

Membrane filtration method:

Test temperature: ..... 20°C
Interfering substances: ..... None
Test strain: ..... *Mycobacterium terrae CIP 104.321.*
Incubation temperature: ..... 37°C
Test date: 8/4/15
Diluent used for the product test solutions: ..... Sterile distilled water
Appearance of product dilutions: ..... colourless, liquid
Appearance of the product during the test: ..... no precipitate
Type of membranes: ..... Cellulose ester, 0.45µm, 47 mm diameter
Reference: 11406-47-ACN

Validation and controls

Validation suspension (Nvo)			Experimental conditions control (A)			Neutraliser toxicity indicator (B)			Method validation (C)		
V_{c1}	68	$\bar{x}$ =101	V_{c1}	69	$\bar{x}$ = 78	V_{c1}	69	$\bar{x}$ = 86	V_{c1}	77	$\bar{x}$ = 87
V_{c2}	72		V_{c2}	72		V_{c2}	57		V_{c2}	72	
$30 \leq \bar{x}$ of $N_{vo} \leq 160$?			$\bar{x}$ *of A* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ *of B* is > 0.5 x $\bar{x}$ of N_{vo}?			$\bar{x}$ of C is > 0.5 x $\bar{x}$ of N_{vo}?		
Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐		Yes ☒	No ☐	

Test suspension and Test

Test suspension (N and N_0)	N	V_{c1}	V_{c2}	N = (111 + 111+9 + 16)/2.2x10^{-7} = 9.05 log N_0 = N/10 = 8.05 log N_0 is between 8.17 and 8.70	Yes	No
	10^{-7}	111	111		X	
	10^{-8}	9	16			

Vc: Number of CFUs counted/ml; N: Number of CFUs in the test suspension; N_0: Number of CFUs in the test mixture; N_a: Number of CFUs counted after contact with the product; N_{v0}: Number of CFUs/ml in dilution of validation suspension; R: Reduction in number of bacteria. Inc: Uncountable.

As indicated in the standard, the concentration of the product used to validate the standard is the highest concentration studied, the 80% concentrated product here.

Notes about the results

- ✓ All controls and the method validation mixture produce values within the baseline limits.
- ✓ At least one product concentration showed a log reduction of at least 4 log. No formation of precipitate during the test.
- ✓ The test suspension (N) is beyond the limits noted in the standard; however, the visible reduction remains above 4 log.

Product conc. and contact time.	Degree of dilution	V_{c1}	V_{c2}	N_a	Log N_a	$\log R$ ($N_0 = 8.05$)
80% 10 minutes	10^0	>165	>165	2850	3.45	**4.60**
	10^{-1}	22*	35*			
	10^{-2}	1	4			
	10^{-3}	0	0			
40% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<1.83
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	Inc*	Inc*			
20% 10 minutes	10^0	Inc	Inc	>1.65 x 10^6	>6.22	<1.83
	10^{-1}	Inc	Inc			
	10^{-2}	Inc	Inc			
	10^{-3}	Inc*	Inc*			

Weighted averages control: D= [(111 + 111) /2] / [(9 + 16) /2] = 8.88
8.88 is between 5 and 15.

Conclusion

The product **formula code F010474V1, batch 4494** used for the manual disinfection of heat-sensitive medical devices of the endoscope type complies with the NF T 72901 standard because it has demonstrated, under the conditions proposed for its use, a capacity to maintain sufficient activity to justify its period of use (7 days) under the following conditions:

-log reduction of at least 5 according to EN 1040 on *P.aeruginosa* and *S.aureus* during the whole test period at the concentration of 8% in 5 minutes of contact.

-log reduction of at least 4 according to EN 14348 on *M.terrae* during the whole test period at 80% concentration in 10 minutes of contact.

To qualify as a disinfectant for medical devices, the product formula code **F010474V1** must be evaluated independently of NF T 72901 and according to the requirements described in NF EN 14885.

Clermont-Ferrand, 05/05/2015.

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Annex 1

Summary sheet (microbiology tests)

Name of product:			
Duration of use of the bath: 7 days			
		Disinfectant with 8-day stability	
		TO	T Final
EN 1040	*Staphylococcus aureus* CIP 4.83	8% 5 minutes	8% 5 minutes
	Pseudomonas aeruginosa CIP 103.467	2% 5 minutes	8% 5 minutes
EN 14347	*Mycobacterium terrae* CIP 104.321	80% 10 minutes	80% 10 minutes

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