



Toulouse, 24th November 2015

STUDY 15-1850

EVALUATION OF THE EFFICACY OF THE SANIVAP SP540 H STEAM DISINFECTION PROCESS COMBINED WITH HYDROGEN PEROXIDE ACCORDING TO A TEST METHOD BASED UPON pr NF T 72-282 AND NF EN 16615

Report on sporicidal (additional strains) activity

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1. Test Laboratory

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2. Identification of the steam disinfection system

Appartus : SANIVAP SP540 H

Serial number : 717 771

Manufacturer: SANIVAP

Process: Steam generator at high temperature and pressure + H₂O₂

Accessories: Microfiber mount (SP240) + microfiber (MV345) or steam lance (SP300)

Remark: for the test the steam level was set at "1".

Disinfectant :	MV 600 (7.5% H ₂ O ₂ solution) (3.5% maximal concentration in the steam flow)
Batch :	SA 201 503 17
Promotor :	SANIVAP
Storage conditions:	Ambiant temperature
Period of testing:	November 2015
Active Substances:	None (bactericidal, fungicidal yeastidal and virucidal activities) Hydrogen peroxide (sporicidal activity)

3. Experimental Conditions

a. Tests micro-organisms

- Sporicidal activity :

- o *Bacillus cereus* (spores) CIP 105.151
- o *Clostridium sporogenes* (spores) NCTC 13366

The conditions of preservation of the microbial strains used are those described in the European standard NF EN 12353(3).

The selected tests surfaces are Stainless steel surface.

b. Diluants and culture media

Interfering substances

3g/L bovine albumin + 3mL of sheep erythrocytes (batch 215)

Diluants

Suspension preparation : EPPI (Cooper, batch 19HD03GA, exp. 03/2017)

Recovery solution: Tryptone, pancreatic digest of casein 1 g ; Tween 80 5g ; Sodium chloride 8.5g ;

Distilled water q.s.p.1000 ml (internal preparation: batches 6252 and 6254)

Filtration membranes

Nitrocellulose membranes 0,45 µm (Millipore, batches F5EA94766 and F5DA72471)

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RESULTS OF DISINFECTION EFFICACY TESTS ON SPORES: BACILLUS AND CLOSTRIDIUM DIFFICILE

Evaluation of the efficacy of SANIVAP steam disinfection equipment SP540H. Disinfection process: steam + solution of hydrogen peroxide at 7.5% concentration. Concentration of hydrogen peroxide after mix with steam: maximum 3.5%.

Number of viable microorganisms on test surfaces before (Nw) and after (Nm) treatment by the SANIVAP steam disinfection process. Mechanical effect (Nm).

Mean of viable microorganisms transferred from the contaminated areas (C4 to C6) to the non-contaminated areas (C1 to C3 and C7 to C15) (N').

R: logarithmic reduction.

	<i>Bacillus cereus</i> CIP 105.151	<i>Clostridium difficile</i> NCTC 13366
Nw (Nb. CFU/ test area)	1,5x10 ⁴	0,66x10 ⁴
Nm (Nb. CFU/ test area)	2,18x10 ⁴	0,67x10 ⁴
Nc ₄	<1	<1
Nc ₅	<1	<1
Nc ₆	<1	1
N' (Nb. CFU test area) C1 to C3 and C7 to C15	<10	<10
N'm (Nb. CFU test area) C1 to C3 and C7 to C15	<10	<10
Logarithmic reduction R	4,3	>3,8

5. Conclusion

According to the conditions of test, the treatment of the test surface with the steam disinfection process **SANIVAP SP540 H combining steam and hydrogen peroxide** (steam value set at 1, processing speed: 10 cm/s, only one pass on the surface) fitted with the microfiber mount (SP240) or the steam lance (SP300) has led to:

- **A sporicidal activity (log reduction \geq 3) on the following strains :**
 - spores de *B. cereus* CIP 105.151
 - spores de *C. difficile* NCTC 13366

In the defined conditions, N_w (and N_m) for *C. difficile* were under 4 log, but a log reduction higher than 3 can be observed.

In conclusion,

As required, the reductions obtained after treatment of the test surface with the **steam disinfection process SANIVAP SP540 H** (steam value set at 1, processing speed: 10 cm/s, one pass on the surface) **combined with H₂O₂** fitted with the microfiber mount (SP240) or the steam lance (SP300) are:

- At least 3 logarithmic units for bacterial spores