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REPORT

Microbiological Investigation of the Decontamination Performance of Caps by a Pulsed Light System from CLARANOR

Accomplished for:
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1 Aim of the investigation

By the following investigation the efficiency of a flash lamp system was studied regarding to the decontamination of *A. brasiliensis* conidiospores in the inner surface of caps provided by the company Claranor. Figure 1 shows the picture of the investigated samples.

Figure 1 Picture of the investigated caps, Bericap 3419

The Claranor Pulsed Light system uses very short (300 µsec) light flashes of high intensity, coming from one Xenon lamp, for the microbiological decontamination of surfaces. To focus the light toward the particular target object, special shaped reflectors are used. In this investigation reflector type 09 020-03 (2-lamps-reflector) was installed.

2 Principle of the Procedure

The decontamination tests of the caps were done according to a method of the association VDMA:
"Code of Practice: Testing the Effectiveness of Aseptic Plants Fitted with Packaging Sterilization Devices" (VDMA July 2008).
The investigation was performed as a challenge test in form of the count-reduction-method.

Using the count-reduction-method, the caps were contaminated with a very high amount of spores. So it can be ensured, that there are enough surviving cells after the decontamination process. The count of surviving cells is determined (see equation 1, "final count").

The efficiency of the decontamination process in each single cap is expressed as the logarithmic count reduction of microorganisms (CR) and can be calculated as described in equation 1 (below).

$$CR = log\ (initial\ count) - log(final\ count)$$

Equation 1: Calculation of the count reduction (CR)

To get the initial count, some references are investigated. These references are treated just as the normal samples but are not exposed in the pulsed light system.

3 Microbiological methods

The artificial inoculation of the caps was done by a spray method with a spore suspension. This process ensures a very even contamination, avoiding cellular multilayer or agglomerates. In this way the spores were homogeneously distributed on whole internal surface in contact with the product. Then the suspension was dried under controlled conditions.

For the pulsed light treatment, the inoculated caps were positioned directly underneath the flash lamp with 2 mm distance between the quartz plate (splinter shield) and the sample. Process parameters were set to 2500 V / 1 and 2 flashes and five parallel samples were investigated.

After the treatment with the flash lamp, the caps were investigated for surviving spores. For detection of the viable count, the spores were removed from the sample surface by a washing process. For this the caps were placed into sterile bags, which were filled with sterile wash solution and shaken for a certain time. Different dilution series were prepared from the suspensions and the aliquots were investigated by pour plate method and filtration.

4 Test – microorganisms

As test microorganisms conidiospores of *Aspergillus brasiliensis* (ATCC 16404 / DSM 1988, former *Aspergillus niger*) were used. This strain is known as one of the most resistant microorganisms against UV-radiation.

5 Results

Untreated samples:

References	CFU/Obj	Arithm. mean
Ref. 1	4,9E+04	**6,4E+04**
Ref. 2	9,7E+04	
Ref. 3	6,4E+04	
Ref. 4	4,8E+04	
Ref. 5	6,0E+04	

Treated samples:

Reflector-No: 09 020-03

Voltage	Flash No.	log-reduction	Mean log-reduction according to VDMA
2500 V	1	> 4,8	**4,5**
		4,8	
		4,5	
		4,1	
		4,8	
	2	> 4,8	**> 4,8**
		> 4,8	
		> 4,8	
		> 4,8	
		> 4,8	

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