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Statement on the test procedure from test report 933322 "Deactivation of aerosolised viruses: bacteriophages MS2".

The company JIMCO A/S commissioned me to review the above mentioned test report with the number 933322 of the Danish Technological Institute, dated September 2020, and to assess its validity with regard to the selected test design. The present opinion refers exclusively to the test design applied. Any statements made in the report on the transferability of the test results to other organisms or viruses, as well as modelling (report 959809 "Modelled theoretical effect of virus UV susceptibility and room size") and calculations (report 954748 "Uncertainty calculation of air purifier test") are not the subject of this opinion.

Conclusion of the study under evaluation:

The efficacy evaluation for the deactivation of aerosolized bacteriophages MS2 was carried out on the basis of a modified test procedure according to ISO 16000-36:2018. The objective of the test procedure was to determine the degree of efficacy of the product MAC500 from the company Jimco A/S against aerosolized bacteriophages MS2. The conclusion reached by the Danish Technological Institute is that, compared to the natural inactivation of the bacteriophages tested, a significantly higher inactivation rate could be achieved by using the MAC500 product. In an airtight test room with a volume of 20 m^3, an inactivation rate of 0.73 to 1.2 log-steps was observed within an operating time of 60 minutes, which is attributed to the use of the product MAC500 (corresponds to a percentage reduction of the bacteriophage concentration by 81.38 % to 93.69 %).

Experimental design oft he study:

The aerosol was generated by means of an atomiser over a period of 15 min and at a pressure of 3.2 bar. A homogeneous aerosol concentration in the test room used was to be ensured by means of a circulating air fan and the MAC 500 device was placed in the centre of the test room on a stainless steel table. Sampling was carried out both for the reference test (air purifier not switched on) and with the MAC500 air purifier switched on at the times 0, 15 min, 30 min, 60 min and 120 min after completion of aerosol production. Details of the experimental set-up can be found in Figure 1 of the Danish Technological Institute report 933322. At the end of the test period, the room was ventilated and the concentration of bacteriophages in the air was determined to ensure that the concentration had been reduced to the baseline level determined

before the aerosol was produced. The aerosolized initial suspension had a concentration of $8x10^9$ PFU/ml. Before aerosolization, no bacteriophages could be detected in the room air. The experimental detection limit is given as $1.5E^{03}$ PFU/m^3.

Assessment of the validity of the study data:

The evaluation of the inactivation kinetics of the bacteriophage MS2 was carried out in comparison to a reference test without the use of the device MAC500. Apart from this adjustment, the tests for product efficacy and for the reference measurement were, as far as can be traced, identical. The air sampling was also carried out identically by means of a stainless steel tube located in the side wall of the room and a pump connected to it.

In addition, background samples were taken to determine the concentration of bacteriophages in the room air before the aerosol was produced. Since no bacteriophages were detected at this time, falsification of the test results by bacteriophage contamination already present in the room air can be ruled out.

It remains open whether a homogeneous distribution of the aerosol in the entire test room was actually achieved through the use of the recirculation fan. Accordingly, this represents a limitation of the study with regard to the desired statement on the effectiveness of the method.

Summary:

Based on the available data, the selected test design appears to be fundamentally suitable for making the desired statement on the deactivation of aerosolised bacteriophages MS2. Based on the data collected, it can be stated that in the comparative study an effectiveness against bacteriophages MS2 was proven by the use of the tested MAC500 method. However, this statement refers exclusively to the area of the room where the sampling took place.

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