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# FINAL REPORT

EN 14683:2005
BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE

PROCEDURE NO. STP0004 REV 02

LABORATORY NO. 498015

PREPARED FOR:

[redacted]

SUBMITTED BY:

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BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE

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| LABORATORY NUMBER: | 498015 |
| PROCEDURE NUMBER: | STP0004 REV 02 |
| SAMPLE SOURCE: | Shanghai Dochem Industries Co., Ltd. |
| SAMPLE IDENTIFICATION: | Refer to Table 1 |
| DEVIATIONS: | None |
| SAMPLE RECEIVED DATE: | 19 Oct 2009 |
| LAB PHASE START DATE: | 02 Nov 2009 |
| LAB PHASE COMPLETION DATE: | 06 Nov 2009 |
| REPORT ISSUE DATE: | 10 Nov 2009 |

INTRODUCTION:

This test procedure was performed to determine the bacterial filtration efficiency (BFE) of various filtration materials, employing a ratio of the bacterial challenge counts to sample effluent counts, to determine percent BFE. This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This test procedure allowed a reproducible bacterial challenge to be delivered to test materials. This procedure has been used with little or no modifications and provides a standard procedure for comparison of filtration materials.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material at a constant flow rate. A digital manometer may be used in place of a water manometer.

Testing was conducted as directed in Annex B (BFE testing) and Annex C (Delta P testing) of EN 14683:2005.

ACCEPTANCE CRITERIA:

The BFE control average was within 2200 ± 500 colony forming units (CFU). A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at sponsor's approval.

The mean particle size (MPS) of the challenge aerosol was maintained at 3.0 ± 0.3 µm.

The average % BFE for the reference material was within the upper and lower control limits established for the BFE test.

The average Delta P result for the reference material was within the upper and lower control limits established for the Delta P test.

BFE PROCEDURE:

Testing was conducted as directed in Annex B of EN 14683:2005. A culture of *Staphylococcus aureus* ATCC #6538 (Designation FDA 209 strain) was diluted in 1.5% peptone water to a precise concentration to yield challenge level counts of 2200 ± 500 colony forming units (CFU) per test sample. The bacterial culture suspension was pumped through a Chicago nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a mean particle size (MPS) of approximately 3.0 ± 0.3 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 L/min (1 cubic foot/min (CFM)). The samples were conditioned for a minimum of four hours prior to testing at 20 ± 2°C and a relative humidity of 65 ± 2%. Test samples, positive controls and reference material received a one minute challenge followed by a one minute vacuum cycle. The samples were tested at normal room temperature. The dimensions of the test samples are located in Table 1. The outside surface of each sample was facing towards the challenge aerosol. The area of each sample tested was approximately 3.0 inches (75 mm) in diameter.

The delivery rate of the challenge also produced a consistent challenge level of 2200 ± 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material were included at the beginning and after the last test sample. A negative control run (without addition of bacterial challenge) was also performed. The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPS of the challenge aerosol.

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and Differential Pressure

The filtration efficiencies were calculated as a percent difference between test sample runs and the control average using the following equation:

$$\% \, BFE = \frac{C - T}{C} \, x \, 100$$

Where: C = Average of control values.
T = Count total for test material.

DELTA P PROCEDURE:

Testing was conducted as directed in Annex C of EN 14683:2005. The ΔP test simply measured the differential air pressure on either side of the test sample using an incline, U-tube, or digital manometer. Test samples were conditioned at 20 ± 2°C and a relative humidity of 65 ± 2% for a minimum of four hours prior to testing. Testing was conducted at a flow rate of 8 liters per minute (Lpm) (volumetric). This value represents a corrected flow rate, which compensates for temperature and altitude differences. At least one reference material is included with each set of test samples.

RESULTS:

The results are summarized in Table 1. Testing met the acceptance criteria previously stated in this report. The average of the BFE and Delta P results met the performance requirements of EN 14683:2005 as Type II, as listed in Table 1, Section 5.2.3 of the standard.

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

JJ /for
Stacey Cushing, B.S.
Study Director

10 Nov 2009
Study Completion Date

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and Differential Pressure

TABLE 1. Results
Sample Identification: flat face mask
BFE Test Date: 03 Nov 2009

| UNIT NUMBER | PERCENT BFE | ΔP (Pa /cm$^2$) |
|---|---|---|
| 1 | 99.8% | 26.9 |
| 2 | 99.9% | 24.9 |
| 3 | >99.9% | 24.6 |
| 4 | 99.9% | 25.4 |
| 5 | 99.7% | 26.5 |

Mean Total Plate Count of Positive Controls: 2314 CFU

Negative Control Plate Count: <1 CFU

Mean Particle Size (MPS): 2.8 µm

Sample Dimensions: 6 ½ inches x 6 inches