



FINAL REPORT

VIRAL FILTRATION EFFICIENCY

PROCEDURE NO. STP0007 REV 02

LABORATORY NO. 489208

PREPARED FOR:

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Page 1 of 6



## VIRAL FILTRATION EFFICIENCY

LABORATORY NUMBER:	489208
PROCEDURE NUMBER:	STP0007 REV 02
SAMPLE SOURCE:	Global Safety First, LLC
SAMPLE IDENTIFICATION:	Refer to Tables 1-2 P.O. #NL 081709
DEVIATIONS:	None
SAMPLE RECEIVED DATE:	19 Aug 2009
LAB PHASE START DATE:	06 Oct 2009
LAB PHASE COMPLETION DATE:	10 Dec 2009
REPORT ISSUE DATE:	11 Dec 2009

### INTRODUCTION:

This procedure was performed to determine the filtration efficiency of various filtration materials, employing a ratio of the challenge to effluent, to determine %VFE. The challenge used in this procedure is the bacteriophage  $\Phi$ X174, which is commonly used in various types of laboratory testing of barrier and filtration materials. This test procedure allows a reproducible challenge to be delivered to the test samples. The VFE test procedure was adapted from the Military standard MIL-M-36954C and ASTM F2101.

### ACCEPTANCE CRITERIA:

The viral filtration efficiency (VFE) control average was  $2200 \pm 500$  plaque forming units (PFU). A VFE run with a control average of less than 1700 PFU shall be unacceptable. Challenges greater than 2700 PFU, but less than 3000 PFU, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 PFU shall be at sponsor's approval.

The mean particle size (MPS) of the challenge aerosol was maintained at  $3.0 \pm 0.3 \mu\text{m}$ .

The average percent viral filtration efficiency (%VFE) for the reference material was within the upper and lower control limits established for the VFE test.

### SAMPLE PREPARATION:

VFE test samples were conditioned for a minimum of 4 hours at  $21 \pm 5^\circ\text{C}$  and  $85 \pm 5\%$  relative humidity prior to testing.

#### TEST PROCEDURE:

The stock bacteriophage  $\Phi$ X174 was prepared by inoculation of  $\Phi$ X174 into a log phase culture of *Escherichia coli*. The culture was shaken at  $37 \pm 2^\circ\text{C}$  until bacterial turbidity cleared. The virus stock was centrifuged to remove large cellular debris and then filtered through a  $0.2 \mu\text{m}$  membrane filter to remove remaining host cell debris. The stock culture was stored at  $2-8^\circ\text{C}$ .

The titer of the bacteriophage was calculated and the titer adjusted before use to yield challenge density that was within  $2200 \pm 500$  PFU per test sample.

The bacteriophage suspension was pumped through a Chicago nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery formed aerosol droplets with a mean particle size (MPS) of approximately  $3.0 \mu\text{m}$ . The droplets were collected in a glass aerosol chamber and drawn through a six stage, viable-particle, Andersen sampler. The flow rate through the test sample and Andersen sampler was maintained at 28.3 Liters per minute (LPM) (1 cubic foot per minute (CFM)).

The Andersen sampler, a sieve sampler, impinges the aerosol droplets onto one of the six agar plates based on size. The agar plates used for assays consisted of 31 mL of bottom agar overlaid with 3 mL of top agar containing *E. coli*. After the challenges, agar plates were incubated at  $37 \pm 2^\circ\text{C}$  for 12-24 hours. The plaques formed by each bacteriophage-laden particle were then counted and converted to probable hit values using the published conversion chart of Andersen.

#### RESULTS:

The filtration efficiency was calculated as a percent difference between test sample runs and runs without a test sample in place using the following equation:

$$\% \text{ VFE} = \frac{\text{Average of control values} - \text{Count total for test material}}{\text{Average of control values}} \times 100$$

Results are summarized in Tables 1-2. Testing met the acceptance criteria previously stated in this report.

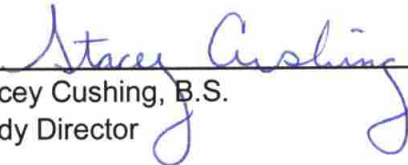


Global Safety First, LLC  
Lab Number 489208

Viral Filtration Efficiency

STATEMENT OF UNCERTAINTY:

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

  
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Stacey Cushing, B.S.  
Study Director

  
\_\_\_\_\_  
Study Completion Date

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TABLE 1. Results  
Sample Identification: GSF-FAY30  
Test Date: 07 Oct 2009

UNIT NUMBER	PERCENT VFE
1	99.9%
2	97.1%
3	>99.9% <sup>a</sup>
4	>99.9% <sup>a</sup>
5	99.9%

CONTROL AVERAGE: 2210 CFU

MEAN PARTICLE SIZE: 2.8 µm

<sup>a</sup> There were no detected plaques on any of the Andersen sampler plates for this sample.

TABLE 2. Re-Test Results  
Sample Identification: GSF-FAY30  
Test Date: 11 Nov 2009

UNIT NUMBER	PERCENT BFE
2	99.5%

CONTROL AVERAGE: 2678 CFU

MEAN PARTICLE SIZE: 3.3 µm



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Viral Filtration Efficiency

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