

# TEST PHYSICAL PROPERTIES

Product: Meltblown60gsm for FFP 3

Test Date: 2021.03.18

Lot No: 21-0318-3

Test Machine: TSI-8130

Item	Unit	Result		
		Max	Min	Average
Appearance	-----	Qualified		
Flow	LPM	60		
Resistance	mmH2O	14.0	12.6	13.1
Penetration	%	0.08	0.06	0.07
Conclusion	This lot is qualified.			

**NOTE:**

Test by paraffin oil.

The physical properties mentioned above represent this lot of non-woven fabric. These values should not be considered as specification values of this type of material.

Shelf time: 1 year (From date of manufacture).

**Material:** 100% polypropylene

**Grade & Applications:** for FFP3 dustproof respirator

**Quality Standard:** EN149-2001+A1-2009,

**Tested by** TSI 8130 OIL 60 LPM

Quality Level	Low Level		Middle Level		High Level	
	Weight g/M <sup>2</sup>	Delta P mmH2O	Weight g/M <sup>2</sup>	Delta P mmH2O	Weight g/M <sup>2</sup>	Delta P mmH2O
FFP3	90-100	20	70-80	18	60-70	13

## Viral Filtration Efficiency (VFE) Final Report

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Test Article: Bill of material RESP-RTF  
Purchase Order: 20200401001  
Study Number: 1307230-S01  
Study Received Date: 05 Jun 2020  
Testing Facility: Nelson Laboratories, LLC  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 16  
Deviation(s): None

**Summary:** The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage  $\Phi$ X174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at  $1.1 - 3.3 \times 10^3$  plaque forming units (PFU) with a mean particle size (MPS) of  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside  
Test Area:  $\sim 40 \text{ cm}^2$   
VFE Flow Rate: 28.3 Liters per minute (L/min)  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Positive Control Average:  $2.5 \times 10^3$  PFU  
Negative Monitor Count:  $< 1$  PFU  
MPS:  $3.0 \mu\text{m}$



Leah Tiberius electronically approved for  
Study Director

James Luskin

22 Jul 2020 23:47 (+00:00)  
Study Completion Date and Time

**Results:**

Test Article Number	Percent VFE (%)
1	>99.9
2	99.8
3	99.7
4	>99.9 <sup>a</sup>
5	>99.9 <sup>a</sup>

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

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request