Cambridge
materials testing limited

6991 Millcreek Drive, Unit 13
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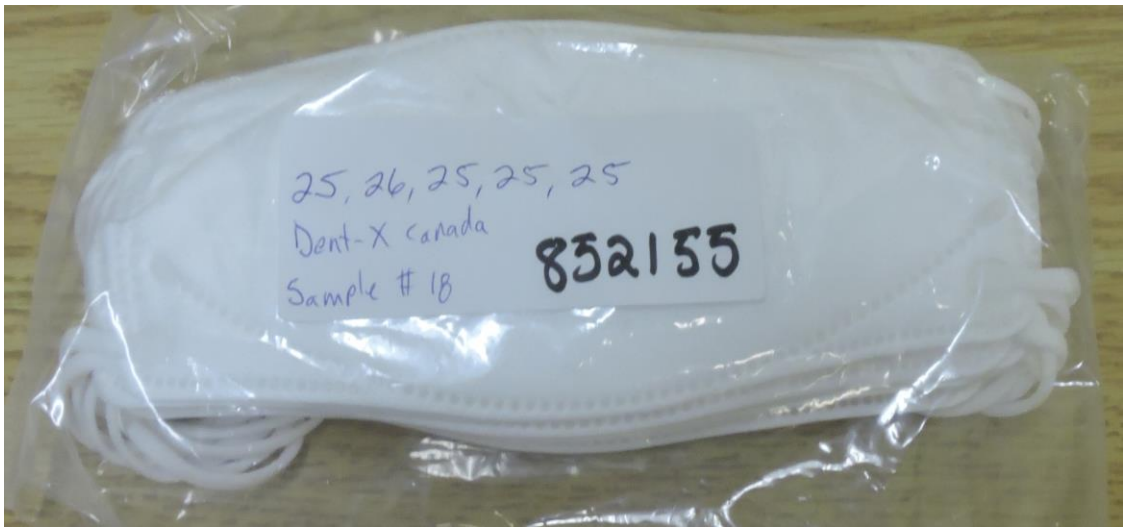
Report For:	Dent-X Canada 311 Bowes Road Main Unit Vaughan, Ontario L4K 1J1 Phone: 416-774-2476 Email: angelina@dent-xcanada.com	**Laboratory #:**	852155-20
		Report Date:	January 14, 2021
		Received Date:	December 29, 2020
Attention:	Angelina W.		
Specimen:	#1: N95 Style Respirators, Sample #18		

TEST REPORT

One specimen, consisting of N95 respirators, was submitted to be tested for synthetic blood penetration, flame spread, particulate filtration efficiency, inhalation/exhalation resistance and bacterial filtration efficiency to determine acceptability with Health Canada Interim Order Guidance Document for N95 respirators.



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Per Stwe Brown
Authorized By Stephen Brown

Per Anamaria Rojas Pineda.
Technician, Anamaria Rojas-Pineda

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SYNTHETIC BLOOD PENETRATION
ASTM F1862/F1862M-17 at 160 mmHg pressure

RESULTS

Specimen #	Test Pressure (mmHg)	Total Number of Specimens	Number of Pass Specimens
1	160	32	32

Note: Acceptable Quality Limit of 4.0% is met for single sampling plan when 29 or more of the 32 tested specimens show pass results.

Material construction type	Not provided/unknown
Supplier	Not provided/unknown
Lot number	Not provided/unknown
Date of receipt	December 29, 2020
Date of test	January 5, 2021
Fluid velocity (cm/s)	641
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	2°
Description target area mask	White center area
Distance from tip cannula to mask (in)	12
Technique to enhance visual detection	Cotton swab used to lightly daub on the surface
Conditioning parameters	21±5°C, 85±5% R.H for minimum of 4 hours

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FLAME SPREAD

The specimen, consisting of 5 masks, was tested in accordance to 16 CFR 1610 (1-1-16 Edition).

	Specimen #	RESULT	CONCLUSION
Specimen #1	1-1	IBE	**Classified as Class 1**
	1-2	IBE	
	1-3	IBE	
	1-4	IBE	
	1-5	IBE	

IBE: Ignited but extinguished

Test: Flame Resistance 45˚ angle test. One-Second Flame Impingement.
Type of fabric: Without a raised fiber surface
Surface tested: Face
Type of test: Original State
Direction tested: Length
Testing Conditioning: Specimens conditioned at 105°C for 30 min, then placed in desiccator
Requirements: The flame spread time for textile products without a raised fibre surface must be greater than 3.5 seconds.

Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.

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PARTICULATE FILTRATION EFFICIENCY

One sample identified as #18- consisting of five specimens, was submitted to be tested for determination of particulate filter efficiency level for N95 or equivalent type respirators. The testing was performed by Kinectrics Inc. (800 Kipling Avenue, Unit 2, M8Z 5G5) based on the TEB-APR-STP-0059 test procedure.

The Kinectrics standard procedure had consisted of the following:

- Conditioning of respirators were performed for 25 ± 1 hour at 85% ± 5% relative humidity and 38ºC ± 2.5ºC and tested within 10 hours of extraction from the conditioning chamber as indicated in NIOSH standard procedure TEB-APR-STP-0059.

- The flat filters meant to be used as filtration media in respirators were challenged for 5-minutes under a flow of 85 L/min ± 1.4 L/min with an aerosol of sodium chloride (NaCl) particles with an average count mean diameter in the range of 0.075 µm ± 0.020 µm with a geometric standard deviation not exceeding 1.86.

- The aerosol concentration was determined on the test day by gravimetric method. The aerosol produced was also subjected to an ionized air stream, to shift the electrically-charged generated aerosol to a neutral state. A forward light scattering photometer was used to determine aerosol concentrations upstream and downstream of the test specimen.

RESULTS

Specimen #	Filtration Efficiency (%)	Result (Pass/Fail)
1-1	99.7	Pass
1-2	99.9	Pass
1-3	>99.9	Pass
1-4	99.8	Pass
1-5	99.8	Pass

REQUIREMENTS

For N95 masks under 42 CFR Part 84.174 the minimum efficiency for each filter must be ≥95%.

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INHALATION/EXHALATION RESISTANCE

The test equipment used in this evaluation is capable of performing airflow resistance measurement as per 42 CRF 84 Subpart K & 84.180. Test was conducted in accordance to NIOSH standard procedure TEB-APR-STP-0003 (exhalation) and TEB-APR-STP-0003 (inhalation). The testing was performed by Kinectrics Inc. (800 Kipling Avenue, Unit 2, M8Z 5G5)

Sample#	Inhalation Resistance (Pa)	Result (Pass/Fail)
1-1	241.2	Pass
1-2	344.2	Fail
1-3	318.7	Pass

Sample#	Exhalation Resistance (Pa)	Result (Pass/Fail)
1-1	199.1	Pass
1-2	205.0	Pass
1-3	192.2	Pass

REQUIREMENTS

For N95 masks under 42 CFR 84.172 the maximum allowable inhalation resistance shall be ≤343 Pa, and exhalation resistance of ≤245 Pa

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BACTERIA FILTRATION EFFICIENCY (BFE)

Testing performed by GAP EnviroMicrobial Services Ltd., 1020 Hargrieve Road, Unit 14, London, Ontario, Canada, N6E 1P5

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19 to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts recovered downstream. A suspension of *S. aureus* was aerosolized using a nebulizer and delivered to the test article at a constant rate with a target delivery rate of $1.7 \times 10^3 - 3.0 \times 10^3$ colony forming units (CFU) per test article with a mean particle size of 3.0 ± 0.3 µm. The aerosolized suspension was drawn through the test article which was clamped in a six stage Andersen air sampler, at a constant flow rate of 28.3 liters per minute (LPM), for collection on bacteriological agar plates.

Challenge Microbe: *Staphylococcus aureus* ATCC 6538
Test Side: Non-defined sheet of material
Area Tested: ~38.5 cm^2
Flow Rate: 28.3 LPM
Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level: 2.2×10^3 CFU
Mean Particle Size: 3.2 µm

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%)
1-1	3	99.9
1-2	2	99.9
1-3	1	>99.9
1-4	2	99.9
1-5	2	99.9

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level
T = Total CFU recovered downstream of test article

REQUIREMENTS

For N95 masks under 42 CFR Part 84 and FDA/NIOSH MOU 225-18-006 the minimum bacterial efficiency shall be ≥95%.