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ANALYTICAL REPORT ID 22-PPE-00337

DATE RECEIVED 02-Aug-2022

REPORT DATE 8-Aug-2022

MANUFACTURER Layfield Canada Ltd.

PRODUCT ID 95PFE-L3 Particulate Respirator LOT/BATCH# 95PFE-L3 Particulate Respirator

MATERIAL SMS

DESCRIPTION Black Masks

MEDICAL MASK TEST SUMMARY

ASTM F2100: Standard Specification for Performance of Materials used in Medical Face Masks

				ASTM F2100	
Test Method	AVERAGED RESULT	Not Rated	Level 1	Level 2	Level 3
Flammability 16 CFR 1610	Class 1	Class 3		Class 1	
Particulate Filtration Efficiency ASTM F2299	99.98	< 95%	≥ 95%	≥ 9	98%
Differential Pressure EN 14683 Annex C	1.83	≥ 6.0 mm H ₂ O/cm ²	< 5.0 mm H ₂ O/cm ²	< 6.0 mm	ı H ₂ O/cm²
Bacterial Filtration Efficiency ASTM F 2101	100.00	< 95%	≥ 95%	≥ 9	98%

Test results only apply to the samples submitted for analysis. Samples are randomly selected for each test from the submitted batch. It is the responsibility of the distributor to ensure the tested batch is compliant to the required sampling methodology as per ANSI/ASQ Z1.4 or ISO 2859-1. Additional test information is available upon request. Kinectrics is accredited to ISO 17025:2017 by the Standards Council of Canada for ASTM F2100

Note: See VCH Report for Fluid Resistance to Synthetic Blood ASTM F1862 test data

FLAMMABILITY

Test Summary

A conditioned mask or test specimen was affixed to a sample holder and placed in a flammability test chamber. The specimen was exposed to a 16 mm flame for 1 second at an angle of 45°. If the material ignited during this exposure, it was noted whether the flame extinguished before spreading, or if it continued to burn. If the specimen continued to burn, the time of flame spread was measured. Any observations of burning behavior were also recorded. The specimen was tested in its original state as directed in 16 CFR Part 1610.6 (a) step 1 - 'Testing in the original state', (2) 'Plain surface textile fabrics'. As medical masks are intended for one-time use 16 CFR Part 1610.6 (b) step 2- 'Refurbishing and testing after refurbishing' was not performed. The tests were performed in accordance with 16 CFR Part 1610 'Standard for the Flammability of Clothing Textiles'

Date Tested 05-Aug-2022 **Test Side:** Outside

Test Type Original State

Direction Tested: Length

Conditioning Parameters 105 +/- 3°C for 30 +/- 2 minutes

Acceptance Criteria Class 1: Burn time ≥ 3.5s

Class 3: Burn time < 3.5s

TEST LOT NUMBER

Time of Flame Spread
DNI

Article No.	Time of Flame Spread
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

DNI: Did not ignite

IBE: Ignited, but extinguished

PARTICULATE FILTRATION EFFICIENCY (PFE)

Test Summary

Filtered and dried air was passed through an atomizer to produce an aerosol containing suspended polystyrene latex (PSL) spheres. The aerosol was then mixed and diluted with additional preconditioned air to produce a stable, non-neutralized, and dried aerosol of latex spheres. The aerosol was passed through the mask material. An optical particle counter was used to sample upstream and downstream aerosol concentrations to determine the particulate filtration efficiency of the mask. The test was conducted in accordance with Test Method ASTM F2299 with the exception that a non-neutralized particle challenge was used in place of a neutralized challenge as per FDA guidance document on surgical facemasks (FDA- 2003-D-0305)

Date Tested 05-Aug-2022

Test Side and Area Inside, Centre (28.3 cm²)

Conditioning Parameters $30-50\% \pm 5\%$ relative humidity and 21 ± 3 °C

Face Velocity 6 to 7 cm/s

Laboratory Conditions 73 % Relative Humidity; 25 °C

Particle Size 0.1 μm

Acceptance Criteria ASTM Level 1: ≥ 95% PFE

ASTM Level 2,3: ≥ 98% PFE

TEST LOT NUMBER

Article No.	PFE %
1	99.98
2	99.98
3	99.97
4	99.98
5	99.98

Article No.	PFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 99.98
Standard Deviation 0.004

DIFFERENTIAL PRESSURE

Test Summary Differential pressure testing was performed to determine the breathability of the

sample material. Air was passed through a prescribed surface area of the sample material at a constant air flow rate of 8 litres per minute, measured by a calibrated flow meter. A manometer was used to measure the differential pressure across the sample.

The test was conducted as directed in EN 14683:2019 Annex C

Date Tested 05-Aug-2022

Test Side and Area Inside, Centre (4.9 cm²)

Conditioning Parameters $85 \pm 5\%$ relative humidity and 21 ± 5 °C for a minimum of 4h

Flow Rate 8 L/min

Acceptance Criteria Flow rate must be maintained at 8 L/min throughout testing

ASTM Level 1: $< 5.0 \text{ mm H}_2\text{O/cm}^2$ ASTM Level 2,3: $< 6.0 \text{ mm H}_2\text{O/cm}^2$

TEST LOT NUMBER

Article No.	Delta P (mm H ₂ O/cm²)
1	1.65
2	1.89
3	1.65
4	2.03
5	1.95

	Article No.	Delta P (mm H ₂ O/cm²)
4	6	n/a
	7	n/a
	8	n/a
	9	n/a
	10	n/a

Average Delta P 1.83 Standard Deviation 0.175

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Summary

The mask was clamped between a six-stage cascade impactor and an aerosol chamber. A bacterial suspension of *Staphylococcus aureus* was introduced into the aerosol chamber using a four-Jet atomizer. The aerosol was drawn through the sample material using a vacuum pump attached to the cascade impactor. The cascade impactor collects aerosol droplets that penetrate the mask material onto agar plates and sorts them by particle size. Positive control samples were also collected with no test specimen clamped in the test apparatus to verify the bacterial challenge rate (upstream counts). Following the incubating period, the colony forming units (CFU) on the agar plates were counted (downstream counts). The ratio of the upstream counts from the positive control, to the downstream counts collected for the test specimen, was calculated and reported as the bacterial filtration efficiency (BFE). This test was conducted in accordance with Test Method ASTM F2101.

Date Tested 04-Aug-2022

Test Side and Area Inside, Centre (40 cm²)

Conditioning Parameters $85 \pm 5\%$ relative humidity and 21 ± 5 °C for a minimum of 4h

Flow Rate 28.3 L/min

Mean Particle Size (MPS)3 μmNegative Control Count0 CFUPositive Control Average2251 CFU

Acceptance Criteria Control average must be 1.7 to 3.0 x 10³ CFU

MPS of aerosol must be $3.0 \pm 0.3 \mu m$

ASTM Level 1: ≥95% BFE

ASTM Level 2 and 3: ≥98% BFE

TEST LOT NUMBER

Article No.	BFE %
1	100
2	100
3	100
4	100
5	100

Article No.	BFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 100 Standard Deviation 0.000