SYNERGEX™ ONE TYPE I

Filtration Media for Medical Face Mask Type I

Filtration Media developed by Berry Global to achieve European Regulation for face masks Type I EN14683:2019[1]

Synergex ONE Type I is an exclusive spunmelt filtration core with unique meltblown technology to help guarantee Bacterial Filtration Efficiency (BFE) and breathability (ΔP), generating comfort and protection to the users.

Outstanding mechanical properties deliver excellent process stability when converting face masks. In addition, the product is low-risk during transport and helps support ease of storage.

Synergex ONE Type I complies with all biocompatibility standards necessary in the manufacturing and use of face masks. Please contact Berry Global Regulatory for additional information and analysis.[2]

26 GSM

Property/Attribute	Test	EN 14683:2019 Type I
Filtration Barrier	Bacterial filtration efficiency [3.0 um]	≥95
Comfort	Differential pressure, ΔP	<4.0

[1] Type I European meets current regulation in Brazil, Colombia, Argentina and South America countries.

[2] It is the customers sole responsibility to verify the properties of the finished product manufactured with Synergex ONE Type I and ensure conformity for any regulatory requirements.

+55 41 33817600 | berryglobal.com

Berry

High-Performance Protection

Trusted supplier & innovative partner across a broad range of filtration applications

WE THANK YOU

Berry

PLEASE, CONTACT US:

Raul Garcia
Sales Director
South America

Jorge Martinez
Sales Director
Mexico & Central America

Brazil:
mayrahofmann@berryglobal.com
mariawosiack@berryglobal.com

Colombia:
fabiodiaz@berryglobal.com

Argentina:
martinbrion@berryglobal.com

Mexico:
jorgetobias@berryglobal.com

Final Remarks

- ✓ There are several Face Masks construction with different level of performance and we have expertise to support customers.
- ✓ Filtermedia plays a key role in the performance and Berry has the portfolio that could match customer´s requirements.
- ✓ Reliable external service providers/laboratories is key factor to guarantee final product performance.
- ✓ Berry Global is your major partner with product portfolio to solve ALL needs regarding protection/filtration/comfort

Berry Complete Portfolio

TRIPLE LAYER SURGICAL FACEMASKS OFFER

Inner Layer

12 to 25 gsm High quality Spunbond white

Filter Media Layer options

20 gsm High quality MELTEX

26 gsm High quality SYNERGEX™ ONE TYPE I

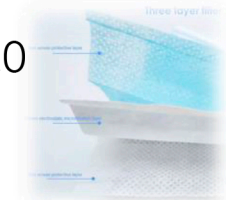
Outer Layer options

12 to 25 gsm High quality Spunbond white

12 to 25 gsm High quality Spunbond Blue

FACEMASK FILTRATION PERFORMANCE

	MELTEX	SYNERGEX™ ONE TYPE I
BFE* :	≥98 %	≥95 %
PFE* :	≥98 %	Not required**
DELTA P* :	~2.0	<4.0



*Triple layer performance with Inner & Outer layers from 12/25 gsm - Berry high quality Spunbond. Delta P could vary according to inner/outer Basis weight.
**EN 14683:2019 does not require PFE

It is the customers sole responsibility to verify the properties of the finished product manufactured with Synergex ONE and Meltex and ensure conformity for any regulatory requirements

Testing and Claims

- Manufacturers **of face masks** are solely responsible to ensure their compliance with NBR ABNT, EN, ASTM, NIOSH, and FDA standards.
- The brand owner of the finished face mask is solely responsible for achieving the certification of claim.
- Converting and transforming of the face mask into a finished product can influence the final performance level achieved

- Raw material producers such as Berry should always test materials externally to check compliance of certain performance levels against regulations – ***this does not guarantee the certification of the finished face mask***

Face Mask Types

It is generally possible to separate face masks into 3 distinct applications

Reference only, each country has appropriated regulation that must be followed.

Physical / Utility (TYPE I)

- Protection from liquids
- No protection from airborne particles
- Can be rigid or flexible
- Single/multi layer construction
- Recommended:

SYNERGEX™ ONE TYPE I

Health services (TYPE I, ASTM L1)

- Protection from liquids
- Some protection against airborne particles
- Multiple layer construction
- Flexible, normally pleated/folded
- Recommended:

MELTEX™

SYNERGEX™ ONE TYPE I

Medical & Industrial (TYPE II/IIR, ASTM L2, L3, N95 & N99)

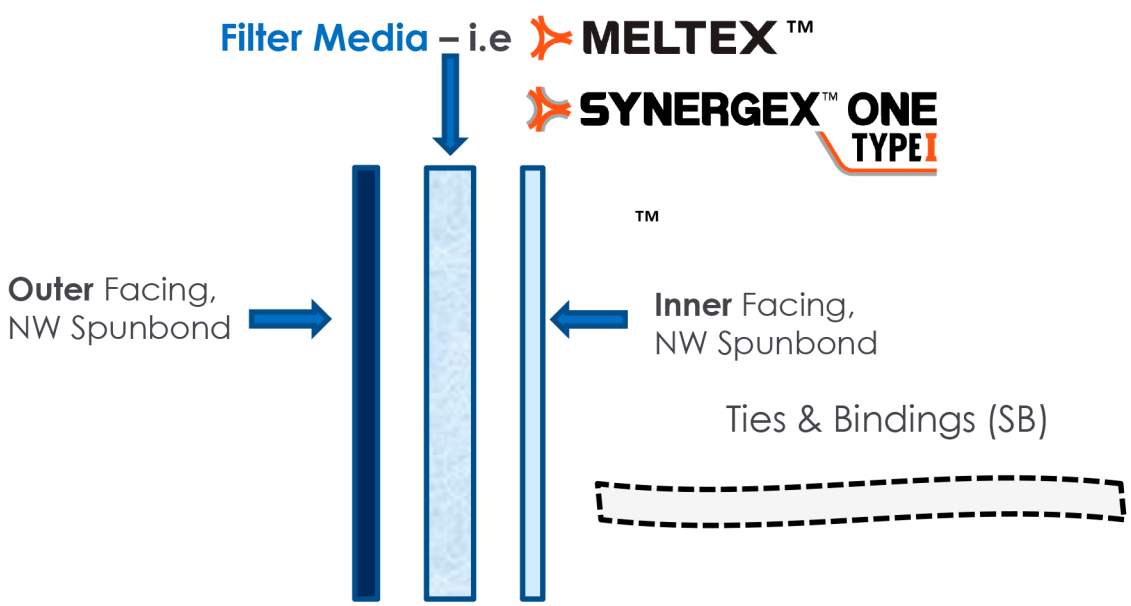
- Protection from airborne particles
- Can protect from liquids, depending on mask chosen
- Multiple layer construction
- Can be rigid or flexible
- Can be folded flat with no air inlet, or with plastic air inlet – depends on manufacturer design
- Recommended:

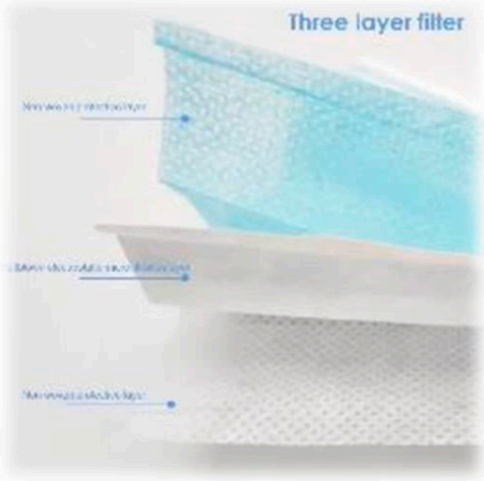
MELTEX™

Face mask construction

Traditionally 3 layer of Nonwoven

- Spunbond / Meltblown / Spunbond





*Variation according to local standards

Face Mask Constructions

OUR SOLUTIONS

Face Mask media alternative

SYNERGEX™ ONE TYPE I

- Multi layer composite material – no lamination needed
- Filtration core of unique meltblown technology
- High Performance with Low Basis Weight: available from 26gsm
- Biocompatibility – information can be shared by Berry Regulatory

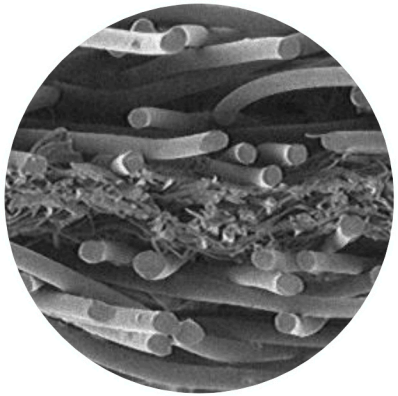
Property/Attribute:	Test:	*EN 14683: 2019*
		Type I
Filtration Barrier	*Bacterial Filtration Efficiency [3.0 um]*	*≥95*
Comfort	*Differential Pressure, ΔP*	<4.0

It is the customers sole responsibility to verify the properties of the finished product manufactured with Synergex ONE and ensure conformity for any regulatory requirements

OUR SOLUTIONS

FACE MASK MEDIA ALTERNATIVE

MELTEX™



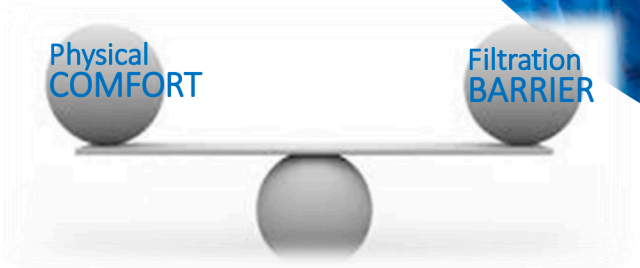
Meltex™ is Berry's meltblown media of choice; requiring the most precise uniformity for air and liquid filtration applications

Improved high dirt-holding capacity
Extends the lifecycle of air filtration devices

Durable proprietary charging technology
Improved filtration efficiency and pressure drop over time

Face mask filtration media
One layer media for Surgical Masks – Level 1, 2 & 3 and solutions for N95 and N99 applications

Liquid filtration
Approved and reliable filtration at a cellular level



Right Balance vs Conventional technologies
Berry proprietary Technology

OUR SOLUTIONS

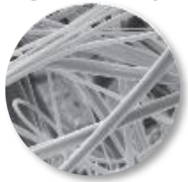
Market leading filtration solutions with superior performance

MELTEX™

Proprietary charged Meltblown

Proprietary charged meltblown

- ✓ ***ASTM Level I, II, III Surgical Mask***
- ✓ ***EN Type I,II, IIR Surgical Mask***
- ✓ ***N95 & N99 respirators facemasks***
- ✓ ***Others high level filtration***



SYNERGEX™ ONE

Multilayer nonwoven composite

With unique meltblown technology – US - *Patent pending*

- ✓ ***EN Type I,IIR Surgical Mask***
- ✓ ***Gowns, Drapes and medical PPE***

Berry Filtration Media

Protection Levels & Standards

MEDICAL FACE MASK TESTS AND REQUIREMENTS

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS

EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2		<40 Pa/cm^2		<60 Pa/cm^2

Latin America Major Regulations (except BR **PFE 98%**)

Source: https://www.nelsonlabs.com/wp-content/uploads/2018/07/Face-Masks-2019.pdf

BFE
Bacteria filtration Efficiency

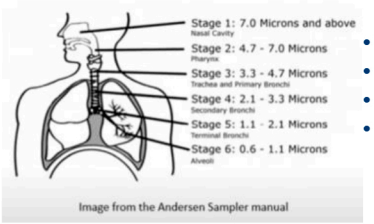


Image from the Andersen Sampler manual

- **28,3L/min**
- **3µm + 1min**
- ***E. Aureus***
- **Andersen Sampler**

PFE
Particles filtration Efficiency

28,3L/min + 0,1 µm

ΔP
Differential Pressure

8 L/min

Splash
Synthetic Blood

80/120/160 mm Hg x 32

Face Mask & Respirators Standards

Products	Key Applications	Types & Tests
 **RESPIRATORS**	 **Industrial & Medical**	US: NIOSH/FDA Requirements ❖ N99 ❖ N95 EU: EN 149:2009 ❖ FFP3 ❖ FFP2 ❖ FFP1
 **FACE MASKS**	 **Utility & Medical**	US: ASTM F2101/FDA ❖ ASTM L3 ❖ ASTM L2 ❖ ASTM L1 EU: EN 14683 ❖ TYPE IIR ❖ TYPE II ❖ TYPE I

BERRY SOLUTIONS:

MELTEX™

SYNERGEX™ ONE

Berry has solutions to achieve all test levels

Materials offered into surgical face mask applications should always be tested against the approached regulation

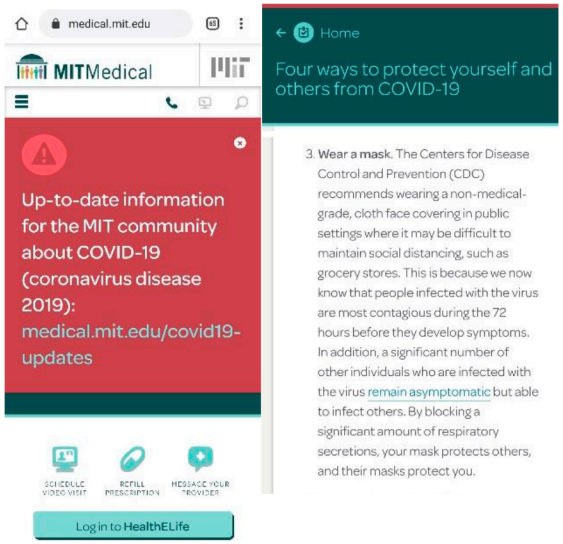
Face Mask & Respirator Standards

Face Masks development – Technology & Regulations

High performance filtermedias & Face Masks construction opportunities

COVID-19 Wear a Facemasks

MIT- Highest importance to support contamination



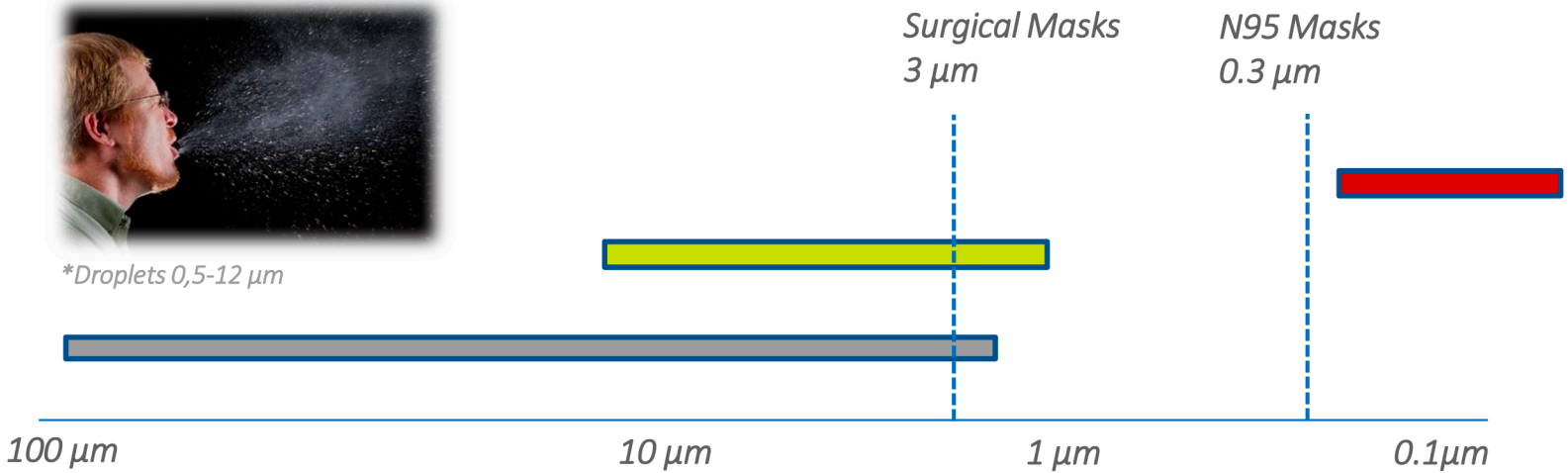
Source: medical/mit.edu

Infection in Surgery

"Wear special hair covers, masks, gowns, and gloves during surgery to keep the surgery area clean." – cdc.gov

Face mask Filtration

*Droplets 0,5-12 µm



Dust

Bacteria

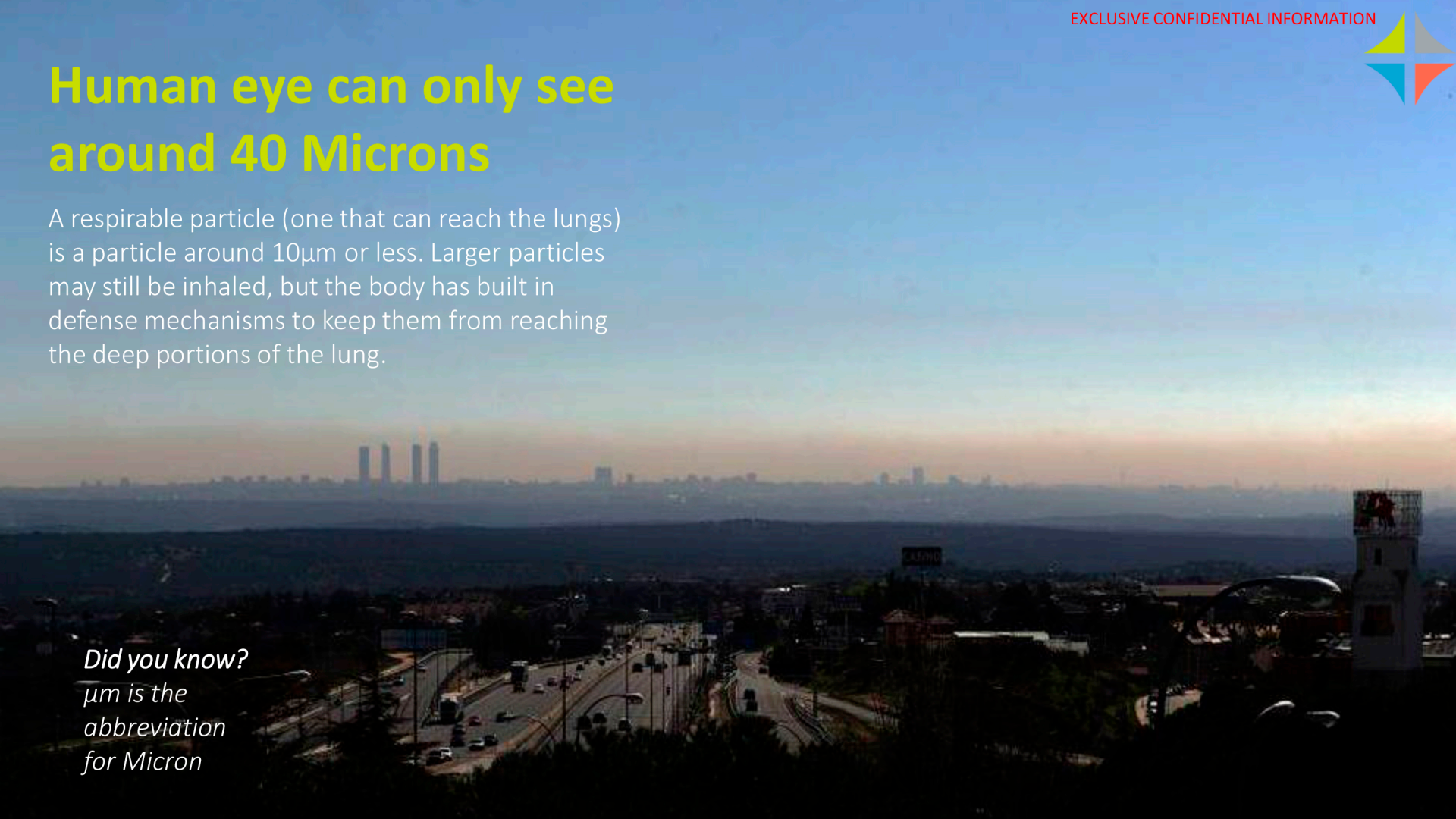
Viruses

Source: EN 14683 - 2019

*Source: TABLE 4-5 Relative Size of Fungus, Bacteria, and Viruses

Human eye can only see around 40 Microns

A respirable particle (one that can reach the lungs) is a particle around 10µm or less. Larger particles may still be inhaled, but the body has built in defense mechanisms to keep them from reaching the deep portions of the lung.



Did you know?
µm is the abbreviation for Micron

Filtration – General information

GENERAL INQUIRES

What learnings can we expect?

- **Is there any differentiation on particles sizes - Bacteria/Virus/Dust? Does all face mask perform the same way?**

- **NO**. Not all face masks have the same performance and there are different protection and comfort levels!

- **What determines the protection level & comfort in a face mask?**

- Protection level is defined by BFE/PFE and Splash test levels. Delta P defines breathability comfort !

- **Are there regulations and different levels of performance for compliance?**

- **YES**, and we should understand accurately during webinar!

Berry Webinar
General Inquires

What learnings can we expect?

Berry Global

World leader in nonwovens, films/laminates & rigid packaging

Divisions : Health, Hygiene and Specialties – Consumer Packaging – Engineered Materials

Global Reach

Latam Strong structure

LATIN AMERICA

U$ 0.6 B

2.000 Employees

7 Technical Facilities:

- Brazil
- Colombia
- Mexico
- Argentina

Product Lines:

- ✓ Nonwovens
- ✓ Laminates
- ✓ Films
- ✓ Printed materials
- ✓ Elastics
- ✓ FIBC

Our Mission

Always Advancing to Protect What's Important

Our Values

Partnerships, Excellence, Growth, Safety

Our Behaviors

United, Focused, Agile, Accountable

Berry at a Glance

Contents

Filter Media for Face Masks & Respirators

CONSTRUCTIONS TO PROVIDE HIGH PERFORMANCE

MELTEX™

SYNERGEX™ ONE

Berry

16th July 2020

Nelson Labs
A Sotera Health company

Sponsor:
Victor Eduardo Gnoatto
Berry Global Group, Inc.
BR 376, 16900. BARRO PRETO
SÃO JOSÉ DOS PINHAIS, PAR, 83015-000
BRAZIL

Differential Pressure (Delta P) Final Report

Test Article:	1) 26 gsm OBEX
Purchase Order:	4500383091
Study Number:	1293185-S02A.1 Amended
Study Received Date:	27 Apr 2020
Study Completion Date:	11 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: STP0004 Rev 18
Deviation(s):	None

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

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:	Embossed Side
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.8	37.0
2	3.7	36.7

Amendment Justification: Per the Sponsor's original request, each sample ID should have its own report.

Alyssa Sanders for James W. Luskin
Study Director

17 JUN 2020
Amended Report Date

1293185-S02

Results:

Test Article Number	Percent BFE (%)
1	97.0
2	97.0

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Amendment Justification: Per the Sponsor's original request, each sample ID should have its own report.

Nelson Labs
A Sotera Health company

Sponsor:
Victor Eduardo Gnoatto
Berry Global Group, Inc.
BR 376, 16900. BARRO PRETO
SÃO JOSÉ DOS PINHAIS, PAR, 83015-000
BRAZIL

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	1) 26 gsm OBEX
Purchase Order:	4500383091
Study Number:	1293185-S01A.1 Amended
Study Received Date:	27 Apr 2020
Study Completion Date:	11 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: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* 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 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

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:	Embossed Side
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Alejandra Sanders for James W. Luskin — Study Director

17 JUN 2020 — Amended Report Date

1293185-S01

1. Aplicação do documento/ Application:

Este documento define as características e propriedades mecânicas de produto manufaturado nas plantas da Berry, de acordo com a tecnologia aqui discriminada.

2. Descrição técnica do produto:

Nãotecido Hidrofóbico: formado por filamentos contínuos de polipropileno através de tecnologia spunbond/Spunmelt consolidados termicamente, sem impregnação;

3. Prazo de Validade:

12 meses (mantido na embalagem original e condições de estocagem recomendadas)

4. NCM:

56031240 para produtos com gramatura de 26 a 70 gsm;

5. Atributos:

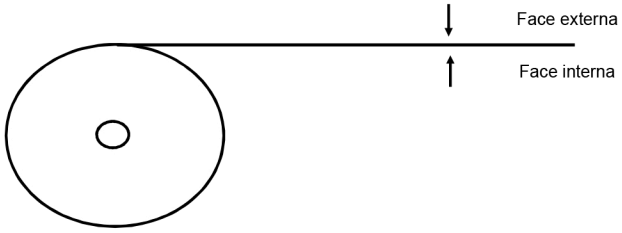
Livre de rugas, dobras, manchas, sujidade, com no máximo 1 emenda por rolo em no máximo 5% do lote.
Rolos com metragem menor do que a nominal poderão ocorrer dentro de um mesmo lote (no máximo 15% menor que a metragem nominal).
Ensaios microbiológicos são realizados periodicamente em todas as plantas da Berry.

6. Status do documento:

Provisória.

7. Características:

Tecnologia: Spunmelt
Tipo de calandra: Oval (Padrão)
Hidrofilicidade: Hidrofóbico
Aditivação: Sem aditivos



8. Segmento/ Aplicação:

HCN INFECTION CONTROL
HCNIC FACEMASK

9. Propriedades Mecânicas:

Propriedade	Método de Teste	Unidade	Tipo	Mínimo Individual	Média Mínimo	Objetivo	Média Máxima	Máximo Individual
Gramatura	WSP 130.1	g/m²	Reporte (CoA)	-	23,40	26,00	28,60	-
Resistência à tração MD	WSP 110.4	N/5cm	Reporte (CoA)	-	35,00	55,00	-	-
Resistência à tração CD	WSP 110.4	N/5cm	Reporte (CoA)	-	20,00	30,00	-	-
Alongamento MD	WSP 110.4	%	Reporte (CoA)	-	20,00	45,00	90,00	-
Alongamento CD	WSP 110.4	%	Reporte (CoA)	-	20,00	50,00	100,00	-
Permeabilidade ao ar	WSP 70.3	m³/m²/min	Reporte (CoA)	-	8,00	10,00	12,00	-
Coluna d'água	WSP 80.6	mbar	Reporte (CoA)	-	30,00	50,00	-	-
Cor - Delta E	IT.CQ.058	-	Controle	-	-	0,00	3,00	-
Alinhamento do tubete	-	mm	Controle	-	-	0,00	3,00	-

Notas:

Os valores de referência discriminados são obtidos através da coleta de dados históricos de produção e referem-se a médias de resultados reportados;
Variáveis tipo "Reporte (CoA)" devem ser reportadas nos certificados de análise de lotes produzidos. Variáveis tipo "Controle" são para controle de processo (interno) e não serão reportadas nos certificados de análise.
-

10. Informações adicionais:

Valores típicos de BFE e ΔP estão anexados a especificação do produto. Os resultados não fazem parte do CoA (Certificado de Análise) e não são reportadoslote por lote.

É responsabilidade do convertedor do produto final acabado, verificar se o produto final atende aos seus requisitos técnicos e regulamentares para a aplicação pretendida.