TPA Network
Research Consortium

Stay Safer Reusable Protective Face Covering

…unique in its ability to offer a meaningful degree of wearer protection

Designed to Comply with New US / International Community Face Covering Standards

MADE IN USA

All royalties to inure to the **TPA NETWORK Research Consortium**, an emerging industry-wide research initiative purpose-built to help health plan sponsors evaluate new medical technologies and health innovations.

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IMPORTANT FACE COVERING PURCHASER ADVISORY

CDC *Scientific Brief* Expands Utility of Face Coverings: New National and International Standards *Pertaining to* General - Purpose Barrier Face Coverings *are Imminent*

Our interest in face coverings is as a result of our creating the *Research Consortium* to evaluate new medical technologies/health innovations for health plan sponsors. The pandemic caused face coverings to become our first project. We studied and wrote extensively about the topic including *The Definitive Employer Guide to Purchasing Face Masks for Your Valued Employees.* To fund our research, we leveraged our expertise to create our patent-pending reusable face covering.

Import of CDC Scientific Brief

The CDC, in a monumental move, recently issued a *Scientific Brief* in that for the first time stated that wearing a face covering can help to reduce the wearers' exposure by filtering infectious droplets. *Community Use of Cloth Masks to Control the Spread of SARS-CoV-2* (found here) states that while it is well known that cloth masks block most large droplets effectively, they also block aerosols and can be excellent source control for exhaled viral particles (noting that some multi-layer masks can perform "on par with surgical masks as barriers for source control".

This acknowledgement of the expanded utility of face coverings to include wearer protection, is consistent with initiatives, *and worldwide*, to develop a community face covering standard that addresses both in- and outbound filtration as a means by which to spurn the creation of better face coverings and to provide users with the confidence they need to feel safe about wearing in public.

Current Regulatory Compliance Requirements

Presently, although no formal national standard exists for general-purpose, community use barrier face coverings in general, various government agencies are responsible for regulating certain aspects of such coverings. By example, both the EPA and FDA are charged with regulating antimicrobial agents based on their intended application. * In general, antimicrobial agents used on inanimate objects are regulated by the EPA as antimicrobial pesticides under FIFRA; and antimicrobials used in or on living animals or humans are regulated by the FDA under FFDCA.

The EPA has established strict rules regarding marketing claims made about the capabilities of anti-microbials. Among them are prohibitions against making claims beyond that of the "treated article" itself. Without specific EPA approval, claims cannot be made about an antimicrobial's protection against or prevention from specific organisms infectious to humans or that of the treated fabric. These prohibitions cover product packaging, advertising and communications.

Face coverings, unless authorized by the EPA, any claim as to an antimicrobial's ability must be limited to the face covering itself; be specific and not unqualified; refrain from referencing health-related microbes and from denoting personal (e.g., "for skin, wound, or respiratory") protection. Graphic representations of the covering's antimicrobial protections cannot include or imply protection of public health significance or take prominence above other normal product claims.

New Community Face Covering Standards

New standards will soon be published that will establish requirements for community face masks throughout Europe and the US. The *American Society for Testing and Materials International (ASTM)* created a workgroup (overseen by the CDC/NIOSH) to develop a "standard" for barrier face coverings that will require meeting minimum performance levels on tests like those used to evaluate respirators to measure leakage, particle filtration and breathability. Specifications are being converted into standards by the European Committee for Standardization (CEN) as well.

The **Research Consortium** has urged international standard organizations to adopt the consumer advisory text below, which we are the first to voluntarily place on our website and promotions:

> *International standards intended to regulate general-purpose face coverings do not address the use of antimicrobial or antiviral materials, finishes, or mechanisms, many of which are subject to oversight by the U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) and may warrant additional testing and regulatory oversight as to their efficacy and safety. Further, there are several aspects that relate to the material composition and design of face coverings that are not addressed by many standards but warrant attention relative to the safety, health, and environmental impact of face coverings including, but not limited to potentially toxic finishes, inhalable substances from materials, and bioburden inhibitors. Understanding this, the* **Research Consortium** *believes it is important that end users become familiar with the specific special claims being made for products and ask for information to verify such claims.*

The Foundation of Our Authority

The **Research Consortium**'s Richard Nicholas has done extensive research on face mask guidelines. He is a member of the *American Association of Textile Chemists & Colorists* committee that created M14-2020 Guidance and Considerations for General Purpose Textile Face Coverings and the *American Society for Testing and Materials International* workgroup that is developing (with the CDC/NIOSH) a soon-to-be-released national "standard" for barrier face coverings.

Mr. Nicholas has reviewed and compared community face covering specifications issued by all of the leading international standards entities having the broadest global impact, as well as those of dozens of other countries that have modified them or developed their own specifications. All totaled, the specifications below have been adopted by more than 120 countries.

- CWA17553 Community Face Coverings: Guide to Minimum Requirements, Methods of Testing and Use
- AFNOR Specification S76-001: Masques Barrières
- NM ST 21.5.200/2020 Réglementation Relative aux Masques de Protection (Islamic Countries)
- TU 13.92.29-005-00302178-2020: Hygienic Face Masks (Russian Federation)
- Health Commission Policy Update: Community Use of Face Masks (African Union)

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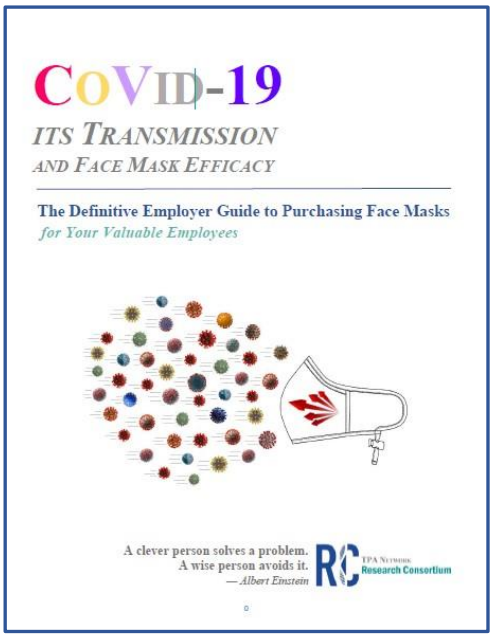
* The FDA regulates all face coverings used for source control as medical devices if they employ an antimicrobial. As such, the **Stay Safer Reusable Protective Face Covering** is presently undergoing lab testing to meet the FDA's review requirements re: the use of antimicrobials. Our covering is undergoing leakage, filtration and air flow testing to meet the requirements of the AATCC M14-2020 Guidance and Considerations for General Purpose Textile Face Coverings specification and the imminent standards of the *ASTM International* and *European Committee for Standardization*.

Although claims are in fact made by manufacturers about an antimicrobial's perceived ability to kill the COVID-19 virus, no entity can justly make such a claim as, to date, there has been no approval, or any form of government-sanctioned testing performed to prove the effectiveness of any antimicrobial agent against COVID-19.

Access Our Deep Knowledge of CoVid-19, Its Transmission and Face Coverings *…and Learn How It Came About It*

The **Research Consortium** was created by a group of healthcare industry veterans to assess new medical technologies and health innovations for health plan sponsors and to guide them on their plan's adoption. ***As it turns out, we found ourselves becoming amateur face covering "experts".***

When CoVid-19 emerged, we refocused our efforts on sourcing a premium-quality reusable face mask for non-healthcare employees. Our 75-page comprehensive study: CoVid-19, its Transmission and Face Mask Efficacy has 176 cited references and has been downloaded thousands of times (to read or download it click on the cover at right).

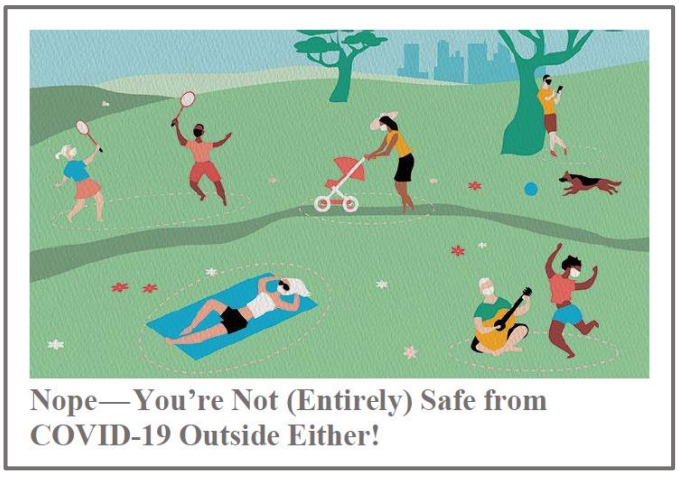


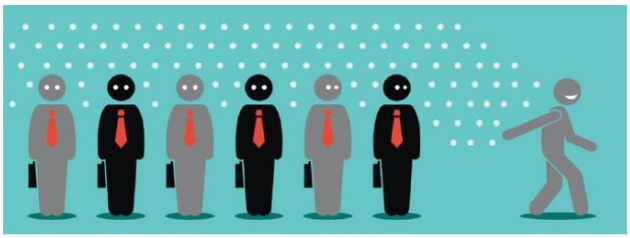
We continue to author short informative articles on a variety of coronavirus-related topics that are discussed in our study in greater detail. They are available on ***Medium***. ***Click here to access all our articles or on the specific article's graphic.***

Each piece details our understanding about the topic or articulates our unique insight or perspective. →

The ease and speed by which CoVid-19 can be spread cannot be overstated. The primary transmission route is through droplets (rain) and tiny aerosol particles (fog) emitted into the air, not just by coughing and sneezing, but also by ← talking and simply breathing.

The airborne transmission of CoVid-19 is enhanced by being outside in a slight breeze. ***A cough or sneeze can launch 1 - 6 billion aerosol particles: experts believe less than 1,000 need to be inhaled to get infected.*** Also, they can travel a long way. →

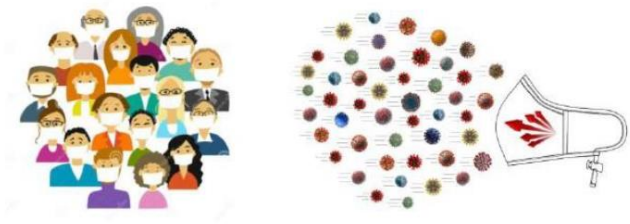




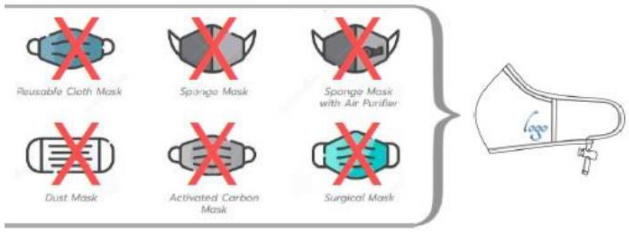
Reimagining Physical Distancing to Include a "Temporal" Dimension

CoVid-19 aerosols are light enough to remain suspended in the air for long periods. It is possible that a man could leave an active viral cloud in a room and infect a woman who enters the room long after the man left it. ***Is there a need to add a third temporal dimension to the physical distancing construct?*** ←

This article discusses the many reasons why face masks should do a lot more than just act as a simple barrier for outbound particles from an infected wearer. While we support their use as a means by which to inhibit community spread, ***we also hear buyers who believe that masks should offer the wearer a meaningful degree of protection against pathogenic transmission.*** →



Should We Demand More from Our Face Masks…Like Wearer Protection?



The Wisdom and Value of Establishing a Company Standard Face Mask

Allowing employees to wear different types of face masks to work is potentially dangerous for the wearer and other workers. It could also carry with it unnecessary OSHA exposure. To be safe ***employers would be wise to establish, clearly communicate and enforce a comprehensive face covering policy and adopt a company-standard face covering.*** ←

The largest publicly-traded health insurers posted a $17 billion profit *in the last quarter*, up 79% from 2019. ***Learn why the ACA (aka Obamacare) incentivizes health plans to buy face masks for your company*** !!! →

Posting Unconscionable Profits, Shouldn't Health Plans Cover Face Masks for their Members?

Are Face Masks Infused with Metals Effective, Safe and Ecofriendly?

Silver- and copper-based antimicrobial agents have many inherent problems and offer little. ← We believe face masks should be toxin free.

The Essential Elements of the Ideal Reusable Face Covering *for Non-Medical Wearers*

A key objective of our research study, CoVid-19, Its Transmission and Face Mask Efficacy was to identify, evaluate and assess the best face covering for non-medical employees. Based on our research, we identified these ***essential characteristics / attributes of the ideal face covering***:

- **Dual Purpose: *Both Source Control and Wearer Protection***
  Cloth face masks are intended to block the outbound transmission of *droplets* from an infected wearer to others. *Most are < 20% efficient at filtering inbound microbes and provide little wearer respiratory protection. Wearers have come to realize that they should ask for more than just source control from their face mask.*

- **Inhibits Dangerous Bio-Burden Build-Up: *Reduces Contamination Risk***
  Viruses can remain active on surfaces for long periods and a covering's outer layer can become a petri dish for dangerous bioburden build-up and cross-contamination. *Face coverings should have at least one safe, effective and enduring means by which to inhibit the growth of, or inactivate, pathogenic microbe colonies.*

- **Facilitates a Snug Fit and Seal: *Ensures Maximum Adjustability***
  Less than a 2% gap in a face covering's seal can reduce its effectiveness by half. *A truly snug fit and tight seal can only be achieved with a proper design and both a flexible nose form and adjustable ear loops.*

- **Balances Effectiveness, Comfort and Breathability: *Enables Extended Safe Wear***
  Correct materials selection, excellent design and quality construction are all needed to *meet the competing requirements of filtration efficiency and breathability (while at the same time being comfortable).*

- **Safe, Healthy, All-Natural and Ecofriendly: *No Toxic Materials***
  Odorless, hypo-allergenic, latex-free, all-natural, environmentally safe, sustainable and *free of metal-based antimicrobial treatments*: these are all needed to ensure and facilitate healthy, extended wear by all.

- **Made in the USA / State of California: *Play the Long Game***
  

  Buying American not only *supports our economy, national security and jobs*, it symbolizes quality. Every component of our product (except for the silk) is made and purchased in the US.

- **A Genuine Value: *Affordable and Cost-Effective***
  Fairly priced considering its intent and purpose of the covering, its useful life and cost-to-wear; It is important to note the keen distinction between the mask's initial price, its cost-of-use and both buyer *and wearer* value.

Given the critical importance of fabric face coverings as a means of source control — and the capability of some to provide a meaningful degree of wearer protection — we believe that each of the requirements detailed above should be fully satisfied.

Employers do not need to unnecessarily expose their workers to the adverse effects of wearing an unhealthy, unsafe or ineffective face mask that might foster a false sense of security or worse.

Research. Evaluate. Purchase.

Leveraging Proven Science and Technology

Why Some Face Covering May be Unsafe and Unhealthy

N95 Respirators are popular because of their perceived *filtration* protection. What actually makes them effective at filtration is not their barrier capability but an electrostatically-charged center layer that attracts and electrocutes negatively-charged microbes. Unfortunately, N95s are built for short-duration one-time use, and they are not available to the public (See discussion below).

Surgical Masks prevent a surgeon's germs from passing to the patient and limit OR sprays and splashes. They are loose-fitting, single-use and offer no electrostatic or antimicrobial protection.

Medical/Procedure Masks are barrier devices for non-OR use with patients. They too are loose-fitting, single-use and offer no electrostatic or antimicrobial protection.

Here are some of the reasons why certain types of face coverings can be unsafe and unhealthy:

- Barrier Protection: Surgical, medical and procedure masks are intended to serve as barrier devices against *droplet*-size particles: they are not intended/built to filter nano-size microbes.
- Respiratory Protection: These masks are not intended to provide the wearer with respiratory protection from inhaling viral *aerosols*. A single droplet (rain) can have 200,000 aerosol particles (fog) and it takes only ~ 1,000 to get infected. Most fabric masks are < 30% efficient.
- Dangerous Bio-Burden Build-Up: CoVid-19 can remain active on non-woven/paper masks for several days; fueling dangerous bio-burden and contamination risk (even with disposal).
- Inappropriate Use: Available and cheap, despite being one-time use, many wear them for days, creating dangerous bioburden / contamination risk and a false sense of wearer security.

Quality disposable face coverings can also be fairly expensive. Used correctly (and frequently as one per day) KN95s can cost ~ $75/month. Surgical and medical masks cost about ~ $10/month.

The *Stay Safer Reusable Protective Face Covering* Difference

Leveraging science and technology, our *patent-pending* protective face covering's design derives in part from a study conducted by researchers at the *University of Chicago* and the world-renown *Argonne National Laboratory*. More than just effective barrier protection, our face covering features *two redundant technologies to attract, secure and inactivate gram-negative microbes.*

All cotton barrier layer with a QAC-based antimicrobial created by *Dow Chemical* that kills enveloped gram-negative microbes

Dual real silk chiffon center layers that create a triboelectric air filter to attract, secure and electrocute gram-negative microbes

Supima® cotton inner layer, with antimicrobial, for soft, snug fit

Able to be safely worn for 90+ days, our face covering's technology supports meaningfully better filtration protection and helps inhibit dangerous bioburden build-up/contamination risk.

The History and Origins of the *Stay Safer Reusable Protective Face Covering*

Our original search was for a face covering that not only served as effective source control but also provided a meaningful degree of protection for the wearer. It had to have all of the elements that we identified as essential, knowing that, as it relates to viral spread and wearer protection, "droplets" aren't the key transmission source: "aerosol" transmission is far more widespread.

Unable to find a reusable face covering that offered meaningful wearer protection, based on our study, and a study conducted by researchers from the *University of Chicago* and the renown *Argonne National Laboratory*, we created a new *type* of reusable face covering. Leveraging proven science and technology, the ***Stay Safer Reusable Protective Face Covering*** is unique in having two *redundant*, highly-effective ways to *capture, secure and kill* gram-negative microbes.

The graphic below details several of its many features:

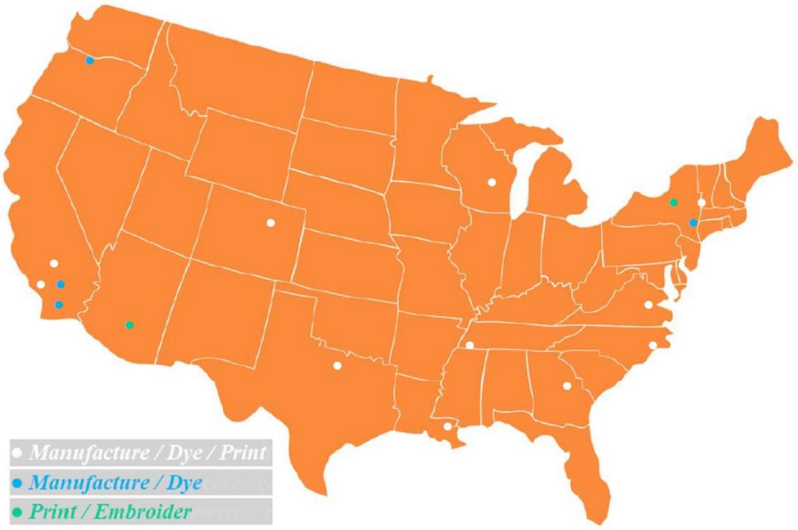
Color and Customization Options

Based on order size and available production lead time, we offer many covering customization options.

Our face coverings are produced in white fabric and then dyed, printed or otherwise customized at regional facilities by custom printers / high-speed embroiders. It can be produced in almost any color (combination) and emblazoned with an organization's name, logo, tagline, slogan, etc. Even its ear straps, and the adjustable push-button locks, may be customized.

Intelligent Production Approach

— *"As they come, we will build it"*



In the past, manufacturers estimated demand, and large cash investments were needed to mass produce and store inventory. Unsold items and materials became waste. Many manufacturers still follow this old production model.

Not surprisingly, the emergence of CoVid-19 created a worldwide surge in demand for the raw materials and components used in face coverings. In turn, this created global shortages, inflated costs and unmet orders.

Production of the ***Stay Safer Reusable Protective Face Covering*** is managed by **Privy Label**, an award-winning, high-tech private label clothing design firm that is forging new ground in an outdated industry with a fresh vision of it. Specializing in curating designs for targeted audiences, it has mastered the nuances of product development and boutique custom products.

The ***Stay Safer Reusable Protective Face Covering*** is made by a digitally connected, localized network of ten domestic MTS/MTO manufacturers, custom printers and high-speed embroiders: each with a history of high-quality production, cost-effectiveness and on-time delivery.

- We have embraced on-demand sourcing and production, to reduce waste and expense and better manage delivery speed, lead times and demand volatility. We leverage make-to-order production to avoid maintaining large inventories and to optimized capacity utilization.
- Our face covering is made in the US / CA with domestically-sourced materials*. We eliminate the waste created by traditional overseas mass production; the unneeded carbon footprint of oceanic shipping; and the harm done by using unhealthy and non-ecofriendly materials.
- Guided by a sophisticated digital spec/tech pack, our network includes large-scale facilities to handle base demand, mid-sized overflow facilities and small-batch cut-make-trim shops.
- Working together, we can meet most production volumes and schedules, minimize waste and deliver consistent customer satisfaction. We have full redundant production capabilities.

* To create a tribo-electric air filter, our covering's center layer is silk chiffon. Because silk has not been made in the US since the 1990s, we source it from a US-owned textile company in India.

Pricing, Subscription Plans and Financing Options

An Exceptional Value on a Price, Cost-per-Use and Service Life Basis

The emergence and persistence of the CoVID-19 crisis continues to have a profound financial and societal impact on organizations of all types and sizes. To help ensure that every employer is able to provide their valued employees with the very best face covering available, we offer the ***Stay Safer Reusable Protective Face Covering*** with easy purchase terms and finance options.

Product Options

We offer two versions of our face covering.

- Our ***Standard*** face covering features a tribo-electric air filter and inner and outer layers made of Supima® cotton fabric that is not manufactured with an antimicrobial agent.
- Our ***Superior*** face covering features a tribo-electric air filter and inner and outer layers of Supima® cotton fabric manufactured with a QAC-based antimicrobial agent.

Minimum Order and Pricing

The ***Stay Safer Reusable Protective Face Covering*** is available on a made-to-order basis with a minimum order quantity (MOQ) of 5,000 units. We are presently accepting orders for delivery 60 days in advance. Our pricing is on a cost-plus basis and volume/customization dependent.

The ***Stay Safer Reusable Protective Face Covering*** will be available on a commercial basis in much smaller quantities in March and on *Amazon* and other online retailers shortly thereafter.

Subscription Plan Arrangement

Employers fund their health plans on a *per employee per month* basis and face coverings must be replaced regularly. Buyers can enjoy the peace of mind of being able to rely upon a scheduled, consistent supply of new face coverings on a timetable that works for them with our subscription plan that features easy PEPM payment terms and scheduled (quarterly) face covering replenishment.

1) a face covering replacement schedule is selected (e.g., bi-monthly, quarterly).
2) a deposit is made equal to ~20% of the est. covering budget over the subscription term; and
3) the remaining balance is paid in equal amounts over the following 11 months.

Supporting Science and Enabling Technology

A clever person solves a problem. A wise person avoids it. — Albert Einstein

I. Self-Sustaining Triboelectric Air Filter

While N95 respirators are considered by many to be the "gold standard" as it relates to face pieces designed to protect the wearer, what makes them effective is not widely known.

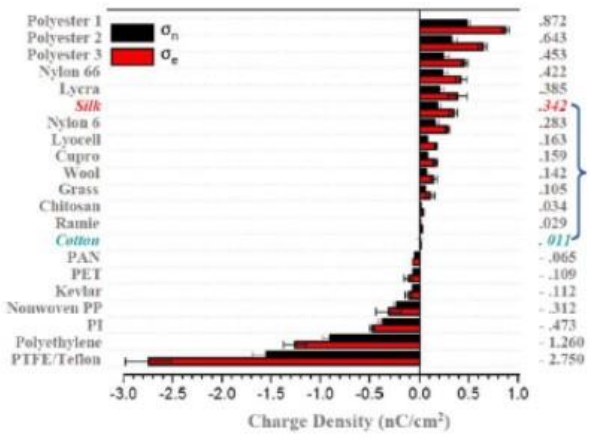
How N95 Respirators Actually Work

- N95s are effective at viral filtration, capturing 95% of particles as small as .3 microns.
- While aerosolized coronavirus-family microbes are far smaller than .3 microns they do not travel alone; they hitch a ride on larger carriers that are caught by its barrier layers.
- Despite this, N95s actually filter smaller particles better than larger ones. Nanosized particles fall subject to the phenomenon of Browning Motion and are propelled at high speed in random directions. *In motion, negatively-charged microbes (e.g., coronaviruses) are attracted to the N95's positively-charged center layer (by electrostatic induction).*
- *The viral microbe's gram-negative protein shell is deactivated (killed) by electrocution.*

Creating a Self-Sustainable, Self-Powered Electrostatic Charge

- A team of *University of Chicago* and *Argonne National Laboratory* researchers found that snug-fitting, multi-layer face coverings made from a combination of cotton with either silk or chiffon fabric can filter nanosized microbes at levels that can match 95% efficiency.
- These fabric combinations create a tribo-electric air filter – similar to the electrostatic layer of an N95 device – to attract, secure and electrocute gram-negative microbials.
- The ***Stay Safer Reusable Protective Face Covering*** *recharges* with rubbing it for only a few seconds and by the aerodynamic friction created by the wearer breathing through it.

sample/fabric	<300 nm average ± error	>300 nm average ± error
N95 (no gap)	85 ± 15	99.9 ± 0.1
N95 (with gap)	34 ± 15	12 ± 3
surgical mask (no gap)	76 ± 22	99.6 ± 0.1
surgical mask (with gap)	50 ± 7	44 ± 3
cotton quilt	96 ± 2	96.1 ± 0.3
quilter's cotton (80 TPI), 1 layer	9 ± 13	14 ± 1
quilter's cotton (80 TPI), 2 layers	38 ± 11	49 ± 3
flannel	57 ± 8	44 ± 2
cotton (600 TPI), 1 layer	79 ± 23	98.4 ± 0.2
cotton (600 TPI), 2 layers	82 ± 19	99.5 ± 0.1
chiffon, 1 layer	67 ± 16	73 ± 2
chiffon, 2 layers	83 ± 9	90 ± 1
natural silk, 1 layer	54 ± 8	56 ± 2
natural silk, 2 layers	65 ± 10	65 ± 2
natural silk, 4 layers	86 ± 5	88 ± 1
hybrid 1: cotton/chiffon	97 ± 2	99.2 ± 0.2
hybrid 2: cotton/silk (no gap)	94 ± 2	98.5 ± 0.2
hybrid 2: cotton/silk (gap)	37 ± 7	32 ± 3
hybrid 3: cotton/flannel	95 ± 2	96 ± 1



Some key design influences derive from a study conducted by researchers at the *University of Chicago* and the world-renown *Argonne National Laboratory*. It found that cotton/silk and cotton/chiffon fabric combinations filtered best by creating a triboelectric air filter (exhibit at left). The exhibit at right (by physicist/scientist Ron Kurtus) illustrates the charge differential between cotton and silk. To improve upon this, our face mask's center layer — silk chiffon — amplifies this friction-generating capability.

II. Safe and Effective Antimicrobial Protection

Anti*bacterials* and anti*microbials* differ regarding the microbes they act upon and how they work. Most are ineffective, many are unhealthy, and some are toxic and outright dangerous.

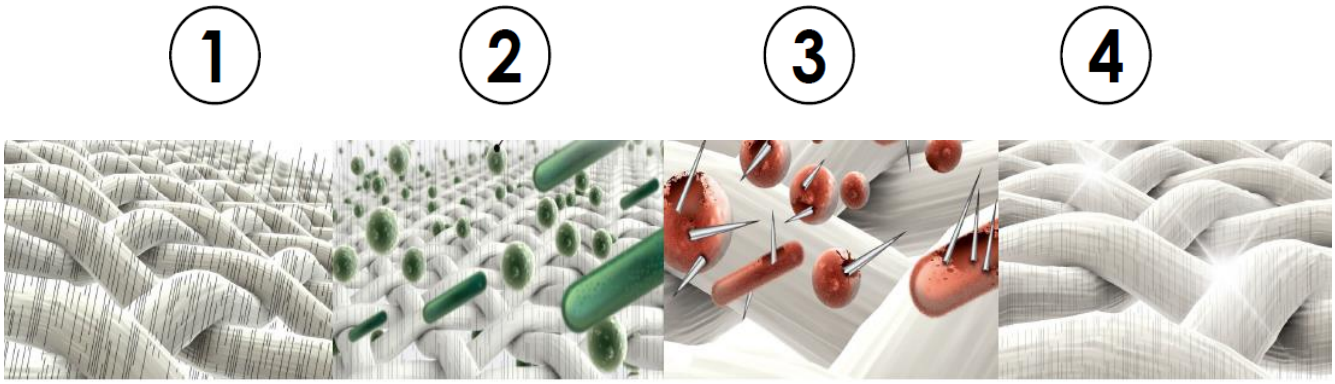
Antimicrobials Are Not All Alike – Avoid Metal-Based Products

- The antimicrobials most commonly used to treat face coverings use unhealthy heavy metal active ingredients such as silver, copper and zinc that are toxic, biocidal and poisonous.
- These toxins are harmful to humans and the environment, unsafe and to be avoided.
- The process works when the metal's toxins are released to penetrate and *poison* the microbe.
- Most metal-based antimicrobials are added to fabrics post-construction and wash off in time.
- As the finite toxin reservoir diminishes, the antimicrobial becomes less effective. As such, face coverings treated with metal-based antimicrobials have a fairly short useful life.

A Proven, Safe, Highly-Effective and Eco-Friendly Antimicrobial

The fabric used on the ***Stay Safer Reusable Protective Face Covering*** outer and inner layers, as well as its ear straps, is made with a highly-effective DRSACI-based QAC antimicrobial.

An alternative, more effective and much safer chemical antimicrobial exists in the form of a quaternary ammonium compound (QAC), a technology pioneered by *Dow Chemical*.



1. QACs molecularly bond to fabric *at manufacture* and become a permanent part of it.
2. Positively-charged QACs attract gram-negative enveloped microbes very effectively.
3. QACs *stab* and *electrocute* microbes; there is *no toxin reservoir* to deplete with use.
4. QACs actually inactivate pathogens to inhibit bioburden build-up / contamination risk.

Our QAC's active ingredient is dimethyloctadecyl (3-trimethoxysilylpropyl) ammonium chloride. DTSACl has an enviable forty-year safety/efficacy profile (available ***here***). To see a two-minute video entitled *How the Si-Quat Biostatic Antimicrobial Works* click ***here***.