MonoFoil™

Clean Redefined⁶

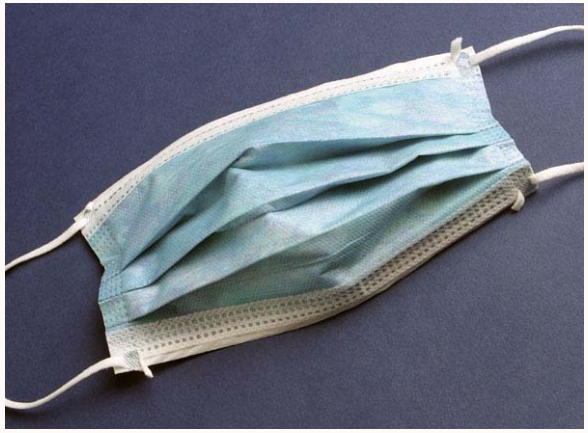
ANTIMICROBIAL ULTRA SENSITIVE FACEMASKS

CŌEUS
technology

The Product

MONOFOIL ANTIMICROBIAL FACEMASK

Treated Mask rinsed with Bromophenol Blue to show adhesion of the MonoFoil Antimicrobial to the substrate.



- **MonoFoil® is a, proprietary antimicrobial agent sprayed onto the outer facing of the disposable surgical facemasks.**
  - Chemically binds to the outer mask surface to create a long-lasting shield against microbial contamination.
  - Due to the mechanical nature of the kill, it will not cause development of more resistant 'superbugs'

Un-Treated Mask rinsed with Bromophenol Blue to show an un-treated substrate.

- **MonoFoil® is safe and effective.**
  - The active material is manufactured from readily available raw materials and then toll-processed in scalable specialty chemical equipment. While MonoFoil® is a new product, the chemically-equivalent monomer has over 30 years of history and use associated with it.

Key Benefits / Features - Customer

- **Facemasks serve as the first line of defense against airborne particles and aerosols by trapping them in the filter media. However, live microorganisms can continue to live on masks.**
  - **According to the Centers for Disease Control (CDC), facemasks should be treated as "contaminated" once worn.**

- **The new MonoFoil® treated Ultra Sensitive facemasks further enhance the functionality of the mask in three ways:**
  1. **Actually killing the harmful microorganisms,**
  2. **Reducing the cross-contamination risk that can result from touching the mask itself and then in turn touching various other unprotected surfaces,**
  3. **Creating a safer environment upon disposal of the mask.**

Key Benefits / Features - Customer

More specifically, "*Better, Faster, Safer*"

- ***Performance***
  1. Efficient broad-spectrum kill (measured by 98.5% to 99.999% reduction in <= 5 minutes). Effective against gram positive and negative bacteria, fungi, algae, and yeasts, such as mold and mildew, ***and viruses (including Influenza A (e.g. H5N1, H1N1, H3N2, etc…)***
  2. Mechanically kills the cell -- will not cause microbial adaptation into "superbugs". Competitive agents such as Silver or Triclosan create "adaptive zones of resistance"
  3. Lifetime residual kill
- ***Toxicity***
  1. Low-toxicity profile (6-pak test data readily available)
  2. EPA registered and approved
- ***Safety***
  1. Proven safety: while this is a new polymer, its chemically-equivalent base-chemistry has over 30 years of history and use associated with it
  2. Non-leaching; No heavy metals; No VOCs (Volatile Organic Compounds); No polychlorinated phenols; No arsenic; No mercury

Current Events: novel H1N1 ("Swine Flu")

Who exactly is the mask protecting?

➢Masks have been portrayed in the media as "*how will it protect me if I wear it?*"*Yes, masks are helpful in protecting the individual,* however the greatest value (especially in a pandemic) is disrupting the transmission of the virus between people.

➢High-quality, FDA-cleared surgical or procedural masks are particularly effective in reducing the transmission of virus FROM THE WEARER to others around them1. This is why the CDC strongly recommends their use by those who are sick to avoid making others sick.

-However, the incubation period, or the period before infectious persons show symptoms can be as long as 24 to 48 hours before symptoms appear, and several days after symptoms have resolved. Further, as many as 40% of infections may be without symptoms at all.

- This means that in the height of a pandemic or epidemic flu season, community transmission can and will occur unknowingly by many asymptomatic carriers.

1 "Face Mask Use and Control of Respiratory Virus Transmission in Households", *Emerging Infection Diseases, Vol. 15, No.2, February 2009*
"Respiratory Protection Against Influenza", *JAMA, Arjun Srinivasan, Trish Pearl, 10/11/2009*
"SHEA Position Statement: Interim Guidance on Infection Control Precautions for Novel Swine-Origin Influenza A H1N1 in Healthcare Facilities", www.shea-online.org, 6/10/2009
"A Quantitative Assessment of the Efficacy of Surgical and N95 Masks to Filter Influenza Virus in Patients with Acute Influenza Infection", *Clinical Infectious Diseases, 2009:49 (July 15)*
"U.S. Pandemic Could Severely Strain Face Mask, Other Supply Pipeline", Virgo Publishing, *Infection Control Today, Kelly Pyrek, 10/4/2008*
"The Science of Sneezing: Modeling Spray Exposure", LiveScience, Jeremy Hsu, 5/8/2009
"Face Protection Effective in Preventing the Spread of Influenza, Study Suggests", *Science Daily, 5/22/2009*

Detailed Product Portfolio

➢**A "family" of antimicrobial facemasks with the same, white, MonoFoil® treated outer layer, but different filter media at three different price points**

-"High End" - *Crosstex Ultra Sensitive Face Mask treated with MonoFoil® Antimicrobial*
-Crosstex White, Ultra Sensitive, Earloop Facemask
-Fluid-resistant outer layer (1 oz. spun bond polypropylene) with white, extra soft, hypoallergenic cellulose inner layer. Void of all inks, dyes and chemicals - will not lint, tear or shred.
-Fluid Resistance - 160mmHg. BFE>99% PFE>99.5% @ 0.1 Micron. Delta P (breathability <3.5 mmH2O/cm². Flame Spread Class 1
-No Latex, CE Marked, FDA Cleared (version without MonoFoil®), Made in the USA
-"Mid Range" - *Crosstex Procedural Plus Face Mask treated with MonoFoil® Antimicrobial*
-Specs same as "High End" except Fluid Resistance - 120mmHg. BFE>95%. Delta P (breathability)=< 4.0 mmH2O/cm². Flame Spread Class 1
-"Value Line" - *Crosstex Isofluid Plus Face Mask treated with MonoFoil® Antimicrobial*
-Specs same as "Mid Range" except Fluid Resistance - 80mmHg.

➢**Shelf life of three (3) years**

Note: mmHg –measure of force per unit area (pressure unit (mm of mercury or torr)
Note: BFE – bacterial filtration efficacy
Note: PFE – particle filtration efficacy @ 0.1 micron

Mask Performance – Core Function

MonoFoil® Antimicrobial facemasks were subject to the same core mask performance metrics as an untreated mask (Nelson Labs May '09)

- DELTA P (Breathability) – Pass (6/1/2009)
  - -MonoFoil® mask - 3.4. Comparable to untreated Crosstex masks. ASTM standard requires the breathability to be less than 5.

- LATEX PARTICLE CHALLENGE – Pass (5/21/2009)
  - -Excellent PFE – 99.5% @ 0.1 Micron
    - -Particle Size = 0.1µm (results as % filtration efficiencies)

- SYNTHETIC BLOOD PENETRATION RESISTANCE (Fluid Resistance)– Pass (5/19/2009)
  - -32 masks tested (29 must pass otherwise the mask fails). Masks tested at 160mmHg -- highest level performance class within the ASTM standards.
    - -Pressure: 160 mmHg. Pass: 29

Microbiology Performance

MonoFoil® facemasks were subject to a wide variety of internal and 3rd party testing against microorganisms for efficacy of the antimicrobial additive

Kill Time	5 Minutes	10 minutes	30 minutes
Staphylococcus aureus	> 99.999%	> 99.999%	NA
MRSA (Methicillin-resistant Staphylococcus aureus)	--	> 99.8%	--
VRE (Vancomycin-resistant Enterococci)	--	99.40%	--
Enterococcus faecalis	> 99.999%	> 99.999%	NA
Salmonella enterica	> 99.99%	> 99.999%	--
Pseudomonas aeruginosa	> 99.999%	> 99.999%	NA
Influenza A*	98.50%	--	99.30%

H3N2 used as a surrogate for all Influenza A viruses including H5N1 (avian or bird flu), novel H1N1 (swine flu), and other strains

Disposal Requirements

Disposal Requirements:

- The MonoFoil® family of masks will require no additional or supplemental disposal guidelines relative to the current methods of disposal for facemasks

- Disposable in common trash receptacle in a healthcare professional or commercial or residential environment

- The addition of MonoFoil® renders the mask safer due to killing (as opposed to just trapping) the microorganisms. Moreover, the fact MonoFoil® has a low-toxicity profile and is biodegradable (it's 97% deionized water) enhances the disposability.

Health & Safety Testing

- **FDA (Biocompatibility)**
  - -Cytotoxicity: Agar Diffusion Assay ISO 10993-5
  - -Intracutaneous Study: Extract ISO 10993-10
  - -Systemic Toxicity: Extract ISO 10993-11

- **EPA (Acute Toxicity)**
  - -Acuter Dermal Toxicity in Rabbits OPPTS No. 870.1200
  - -Acute Dermal Irritation in Rabbits OPPTS No. 870.2500
  - -Acute Eye Irritation in Rabbits OPPTS 870.240
  - -Acute Oral Toxicity Study (UDP) in Rats OPPTS 870.1100
  - -Acute Inhalation Toxicity Study in Rabbits OPPTS 870.130
  - -Skin Sensitation: Local Lymph Node Assay in Mice OPPTS 870.260

Health & Safety Performance

- MonoFoil® Antimicrobial has undergone rigorous acute toxicity testing as required by the US EPA for antimicrobials.

- It has been found to have no untoward effects with the exception of eye irritation from the MonoFoil® Antimicrobial powder, which was expected.

- GLP testing concluded that MonoFoil® Antimicrobial has an extremely low toxicity profile and is not a dermal irritant, skin sensitizer, or ingestion or inhalation hazard.

- When compared to competitive antimicrobials, the safety MonoFoil® Antimicrobial is unique in that it contains no VOC's, polychorinated phenols, or heavy metals.

Biocompatibility Testing

- **NAMSA USP Systemic Toxicity Study:**
  - -Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts

- **NAMSA Cytotoxicity Study Using the USP Agar Diffusion Method:**
  - -Under the conditions of this study, the extract showed no evidence of causing any cell lysis or toxicity. The test article extract met the requirements of the USP since the grade was less than or equal to a grade 2 (mild reactivity)

- **NAMSA USP Intracutaneous Study:**
  - -Under the conditions of this study, there was no evidence of significant irritation from the extracts injected intracutaneously into the rabbits

Intellectual Property

Coeus Technology, Inc has the following IP profile:

- EPA Label (EPA Reg. No. 87538-1) Un-Conditionally Registered
- Trade Secret Formulation processes (Uniform Trade Secrets Act. Civil Code Section 3426-3426.11)

Regulatory Profile

- The EPA approved a MonoFoil® Antimicrobial label on July 16, 2010 (No. 87538-1)
  - The MonoFoil® product has been Un-Conditionally EPA approved. EPA Reg. No. 83019-1

http://www.coeustechnology.com/monofoil/certifications/monofoilEPAregistration.pdf.
http://www.coeustechnology.com/monofoil/certifications/MaterialSafetyDataSheet.pdf

- Within the United States, the sale of face masks treated with MonoFoil® Antimicrobial for medical applications is subject to a 510(k) clearance by the U.S. Food and Drug Administration. At this time (Oct 2010), Coeus is awaiting publication of the latest revision of the FDA Guidance Document pertaining to antimicrobial treatments of medical devices prior to the filing of its 510(k) Premarket Notification submission.
  - As of Oct 2010, the MonoFoil® Ultra Sensitive mask is thus **for EXPORT ONLY in any arenas where the FDA has authority**

- Coeus has submitted an application to the U.S. Environmental Protection Agency covering the sale of MonoFoil® treated masks in the United States for non-medical applications.
  - As of Oct 2010, Coeus is awaiting a response from the EPA