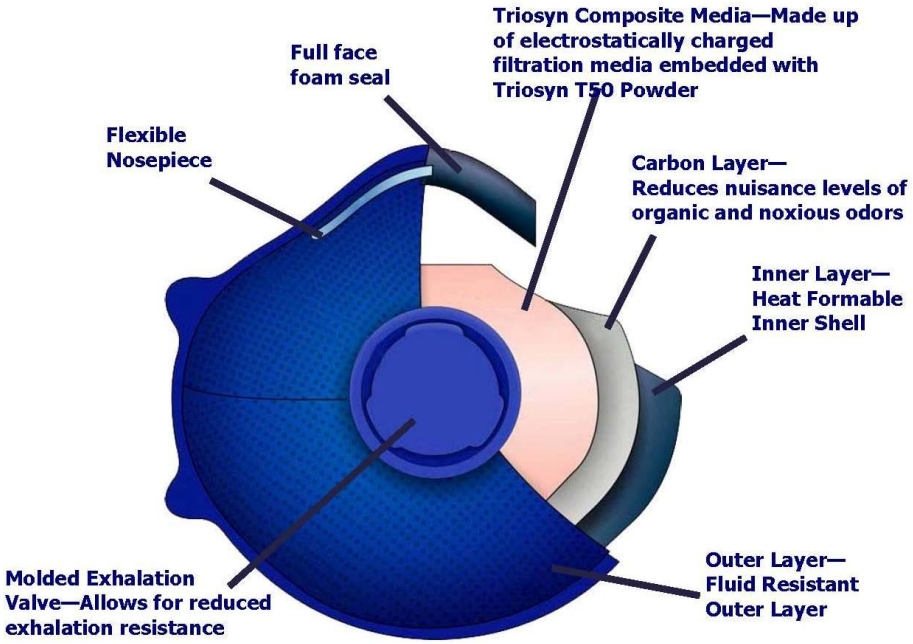
Union Springs Pharmaceuticals
T-5000 Series Respirator with Triosyn®
White Paper

More than 15 years of research are behind the creation of the Triosyn® technology and Union Springs T-5000 series respirators. More than 100 patents and patents pending are associated with the Triosyn technology. **The data from these studies show the superior viral and bacterial protection, face fit, and fluid resistance provided by the T-5000 series respirators.** The results from these studies are the subject of this White Paper.

I. Technology

The T5000 series respirators utilize a multi-layer construction to provide filtration and repellency properties. Figure 1 provides a diagram of the construction of the respirators.

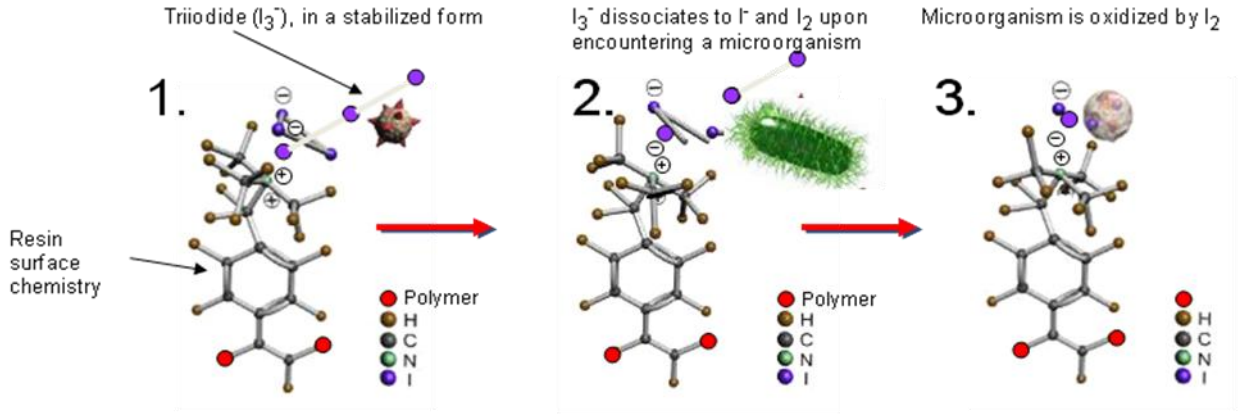
Figure 1



Triosyn resin embedded on the filtration media is a broad spectrum polymer with iodine which destroys dangerous organisms through a proprietary demand-release delivery mechanism. Triosyn is activated by its strong attraction to a passing microorganism. The triiodide form of iodine (I_3^-) present on the Triosyn polymer can release I_2 as the active antimicrobial to destroy microorganisms. This results in the transfer of molecular iodine from the resin to the charged surface proteins of the microorganism.

Figure 2 below shows the chemical structure and mechanism of action. The iodine immediately oxidizes the proteins on the microorganism's surface, rendering it harmless. Microorganisms possess the electrochemical charge that activates the Triosyn demand-release mechanism.

Figure 2



II. Antimicrobial Efficacy of the Triosyn Chemistry

Extensive testing on the Triosyn technology has been completed in order to validate its performance. Figure 3 provides a list of the various pathogenic materials that are inactivated with the Triosyn technology. An overview of the testing completed on a selection of these pathogens is included as part of this document.

Figure 3

Viruses	Bacteria	Spores	Fungi	Protozoa
Phix174 Coliphage Human Immuno. Virus (HIV) MS2 Coliphage Newcastle Disease Virus Poliovirus Type 1 Rotavirus SA-11 SARS coronavirus **Avian influenza A** **Human influenza A subtype H1N1**	*Brevibacteria* *Brucella abortus* *Enterobacter aerogenes* *Enterococcus faecalis* *Erwinia herbicola* *Francisella tularensis* *Klebsiella pneumoniae* *Klebsiella terrigena* *Legionella sp.* *Micrococcus luteus* *Meth.-Res. Staphy. aureus (MRSA)* *Proteus mirabilis* *Pseudomonas aeruginosa* *Pseudomonas pseudomallei* *Salmonella sp.* *Serratia marcescens* *Shigella flexneri* *Staphylococcus aureus* *Staphylococcus epidermidis*	*Bacillus anthracis* *Bacillus atrophaeus* *Bacillus globigii* *Bacillus subtilis*	*Aureobasidium pullulans* *Aspergillus niger* *Candida albicans* *Cladosporium herbarum* *Penicillium citrinum* *Penicillium sp.* *Rhodotorula rubra* *Trichophyton mentagrophytes*	*Cryptosporidium parvum* *Giardia lamblia* *Giardia muris*

Figure 4 demonstrates the efficacy of the Triosyn technology against some of the pathogens shown above. An overview of the methodology for the testing of several of these pathogens is provided throughout this document.

Figure 4

Sample Listing of Test Results		
Microbial Class	**Challenge**	**Results**
Virus	Avian Influenza A	≥99.9998% reduction
Bacteria	Staph. Aureus	>99.9946% reduction
	K. pneumoniae	>99.9979% reduction
Bacterial Spores	B. anthracis	>99% reduction
	B. subtilis	>99.983562% reduction
Fungi	Aspergillus niger	>99.958904% reduction
Protozoa	C. parvum	3 log reduction

Human Immunodeficiency Virus

In a study completed by the Department of Microbiology and Immunology at the University of Montreal, the respirator filters comprised of 2.0 g of resin were tested for efficacy against a stock suspension of Human Immunodeficiency Virus (HIV, HxBRU laboratory isolate) in a phosphate buffered saline solution (PBS) at a titer of 5.0 X 10^7. [1] The filters were tested at a flow rate of 100ml/min and a volume of challenge water of 500ml. Sampling was performed at 10ml, 100ml, and 500ml. A positive control was performed. Samples were immediately frozen at -80°C. After thawing, all assays were performed in duplicate including the immunofluorescence detection assay.

Figure 5: Efficacy Against HIV (HxBRU isolate)

	HIV concentration ($TCID_{50}$ / ml)		
Volume passed	10 ml	100ml	500ml
Positive Control	5.0E+07	5.0E+07	5.0E+07
Triosyn Filtration	0	0	0

$TCID_{50}$: Tissue Culture Infectious Dose 50% 5.0E+07

As Figure 5 shows, no viral unit (HIV) was detected in the sampled water at the various volumes tested. The Triosyn filters were shown to inactivate HIV at a concentration of 5.0X10^7 with a flow of 100 ml / min for 500ml.

Influenza A Virus

Testing was conducted by ATS Labs on the air filtration membrane of the T5000-series respirators using the Hong Kong strain of Influenza A virus (H3N2).[2] Two squares of the test substance were each inoculated with a 0.1ml aliquot of the virus at staggered intervals. The squares remained in the dark at 20.0°C in a relative humidity level of 42% for 6 hours. Immediately following the exposure time, the test samples were transferred to individual sterile tubes containing 3.0 ml of test medium and vortex mixed for ≥30 seconds. The liquid was removed from the tubes and passed through individual Sephadex columns. The filtrates were then tittered by a 10-fold serial dilution (0.1ml filtrate + 0.9 ml test medium) and assayed for infectivity and/or cytotoxicity. Figure 6 shows the serial dilution results from the test samples and the concentration of live virus present after exposure to the filtration membrane samples for a period of 6 hours.

Figure 6: Influenza A Virus Serial Dilution Results

Dilution	Input (zero time) Virus Control		Virus Control (6 Hour Exposure Time)		Triosyn Antimicrobial Air Filtration Membrane (6 Hour Exposure Time)	
	Replicate #1	Replicate #2	Replicate #1	Replicate #2	Replicate #1	Replicate #2
Cell Control	0000	0000	0000	0000	0000	0000
$10^{-1.48}$	++++	++++	++++	++++	0000	0000
$10^{-2.48}$	++++	++++	++++	++++	0000	0000
$10^{-3.48}$	++++	++++	++++	++++	0000	0000
$10^{-4.48}$	++++	++++	++++	++++	0000	0000
$10^{-5.48}$	++++	++++	++++	0+++	0000	0000
$10^{-6.48}$	+++0	++00	++00	000+	0000	0000
$10^{-7.48}$	0000	0000	0000	0000	0000	0000
$TCID_{50}$ /0.1 ml	$10^{6.73}$	$10^{6.48}$	$10^{6.48}$	$10^{5.98}$	$\leq 10^{0.98}$	$\leq 10^{0.98}$
Average $TCID_{50}$ / 0.1ml	$10^{6.62}$		$10^{6.30}$		$\leq 10^{0.98}$	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control indicate that the test substance was neutralized at $TCID_{50}$ of ≤0.98 log_{10}. The dilution results associated with this are shown in Figure 7.

Figure 7: Dilution Results

Dilution	Cytotoxicity Control	Neutralization Control
Cell Control	0000	0000
$10^{-1.48}$	0000	++++
$10^{-2.48}$	0000	++++
$10^{-3.48}$	0000	++++
$TCID_{50}$ /0.1 ml	$\leq 10^{0.98}$	See below

(+) = Positive for the presence of test virus
(0)= No test virus recovered and/or no cytotoxicity present

Under the conditions of this investigation, Triosyn antimicrobial air filtration membranes from the T5000-Series respirators demonstrated inactivation of the Influenza A virus following a 6-hour exposure time in the dark at 20.0°C in a relative humidity of 42%. Taking the cytotoxicity and neutralization controls results into consideration, an average percent reduction in viral titer of ≥99.9998% was demonstrated as compared to the results of the average input (zero time) virus control. The average log reduction in viral titer was ≥5.64 $\log_{10}$.

SARS Coronavirus

Testing of the self-decontamination performance of the Triosyn-treated respirator media against the SARS CoronaVirus (SARS-CoV) was completed by the National Microbiology Laboratory's Office of Biosafety and Environment for Health Canada. [3]

Circular swatches of the media (48 mm in diameter) are first inoculated with high concentrations of the virus. These samples are then incubated at 20°C for the established contact times. After the incubation period, the remaining viable organisms are eluted from the media samples and assayed. The performance of the respirator media is then demonstrated by the comparison of the recovered viral concentration on the incubated facemask media samples to the viral challenge concentration of the initial inoculation.

Figure 8

Contact Periods	Challenge Concentration (TCID50* units / ml)	Untreated (blank) Media n=3 (TCID50* units / ml)	Triosyn-treated Media n=3 (TCID50* units / ml)
10 minutes	1×10^9	$>1 \times 10^8$	1×10^6
60 minutes	1×10^9	$>1 \times 10^8$	1×10^4
24 hours	1×10^9	$>1 \times 10^8$	< 10

- All values refer to approximate titers established by TCID50. TCID50 is performed by looking at three duplicates (total of 6) of each sample diluted 1:10 from undiluted to the 10E-7 dilution.

Figure 8 shows that the Triosyn-treated media provides a substantial decrease in the concentration. Note that here the sensitivity of the assay was 10E1 and 10E8 was the last dilution included.

Bacteria/Spore efficacy

In a study completed by Nelson Laboratories, an independent testing laboratory, swatches of the Triosyn treated respirator media were evaluated for their performance against several organisms. [4] 48mm swatches of the filter media were inoculated along with positive and negative controls. The samples were incubated at 37 ±2°C for the designated time intervals. At time 0 and 24 hours, the samples were extracted by removing the sample swatches from the petri dish and placing them into 100ml bottles containing THIO25. The bottles were shaken manually for 1 minute to extract the surviving organisms. Extracts from each sample were diluted with sterile water blanks and plate counts were performed in triplicate by plating 0.5ml onto SCDA. Figures 9, 10, and 11 show the results of this testing and the efficacy of the Triosyn treated media at reducing pathogen load.

Figure 9: Results for Staphylococcus *aureus*

Sample Identification	Exposure Intervals	Average Control Titer at Time Zero (CFU)	Average Recovered (CFU)	Percentage Reduction (%)	Log10 Reduction
Hp treated	0 hour	~7.8×10^6	6.7×10^6	13.304721	0.06
	24 hour	~7.8×10^6	<2.0×10^2	>99.997425	>4.59
Hp control	0 hour	~7.8×10^6	~7.8×10^6	0.000000	0.00
	24 hour	~7.8×10^6	3.3×10^6	57.381974	0.37

Organism Titer = ~5.7×10^6 CFU/mL

Figure 10: Results for Klebsiella *pneumoniae*

Sample Identification	Exposure Intervals	Average Control Titer at Time Zero (CFU)	Average Recovered (CFU)	Percentage Reduction (%)	Log10 Reduction
Hp treated	0 hour	1.4×10^7	1.4×10^7	2.843602	0.01
	24 hour	1.4×10^7	<1.3×10^3	>99.990758	>4.03
Hp control	0 hour	1.4×10^7	1.4×10^7	0.000000	0.00
	24 hour	1.4×10^7	6.4×10^6	54.739336	0.34

Organism Titer = 1.4×10^7 CFU/mL

Figure 11: Results for Bacillus *subtilis*

Sample Identification	Exposure Intervals	Average Control Titer at Time Zero (CFU)	Average Recovered (CFU)	Percentage Reduction (%)	Log10 Reduction
Hp treated	0 hour	1.2×10^6	1.4×10^6	-16.438356	-0.07
	24 hour	1.2×10^6	<2.0×10^2	>99.983562	>3.78
Hp control	0 hour	1.2×10^6	1.2×10^6	0.000000	0.00
	24 hour	1.2×10^6	8.9×10^6	-633.424658	-0.87

Organism Titer = 1.4×10^6 spores/mL

The Triosyn-treated media was shown to provide a >99.98% reduction in all pathogens tested.

Fungal Efficacy

The efficacy of the Triosyn treated media against a form of fungus was tested by Nelson Laboratories, an independent testing laboratory. [5] Samples of Triosyn treated media approximately 48mm in diameter were inoculated with challenge by adding a 1.0mL aliquot of an approximate 10^6 conidia/mL suspension directly onto each test sample. The samples were held at 20-25°C for the defined time intervals shown below. At the end of these time points the surviving organisms were extracted with Thioglycollate broth with 0.25% Sodium Thiosulfate (THIO25) and plate counts were performed. All tests were performed in duplicate, including triplicate plate counts. Figure 12 shows the effect of the treated surface on the organism population at the set exposure times.

Figure 12: Results for *Aspergillus niger*

Test Organism	Exposure Intervals	Average Control Titer At Time Zero (CFU)	Average Recovered (CFU)	Percentage Reduction (%)	Log_{10} Reduction
Aspergillus niger	0 hour	4.9×10^5	6.1×10^5	-24.657534%	-0.10
	24 hour	4.9×10^5	$<2.0 \times 10^2$	>99.958904%	>3.39
Control	0 hour	4.9×10^5	4.9×10^5	0.000000%	0.00
	24 hour	4.9×10^5	6.1×10^5	-25.342466%	-0.10

The evaluation shows that Triosyn provides a >99.9% reduction in the *Aspergillus* niger fungus after 24 hours. The control showed a ~25% increase in the fungus after the same period of time.

III. Viral Filtration efficiency

Respirators are tested for their filtration efficiency by NIOSH using a 20-minute challenge with salt particles that measure 0.3 microns (µm). These particles are directed against the center portion of the respirator, bypassing the edges which might include staples. Unlike the salt particle test methodology, viral aerosolized particles measuring approximately 0.155 microns were used in the testing of these products. The entire surface area of these respirators is challenged with these live viruses under high humidity to reflect exhalation moisture.

SARS Coronavirus Filtration Efficiency

A study was completed by the National Microbiology Laboratory at Health Canada to determine the efficiency of the Triosyn treated respirator media against an aerosol challenge of SARS Coronavirus (SARS-CoV). [6]

A suspension of the SARS Coronavirus was nebulized by a 6-jet Collison nebulizer, generating a bioaerosol with droplets of an approximate mean diameter of 2µm. A vacuum pump pulls the contaminated air through the AFMs at a flow rate representative of individual protection, and the filtered air is collected in All Stainless Steel Impingers (ASSIs). 47mm diameter swatches (12.56 cm^2) of the filtering material were tested, excluding the inner and outer non-filtering shell liners. These samples were evaluated against the aerosol challenge of the virus at 4.3LPM at several different points in time. The filtration efficiency of the AFMs is calculated by determining the airborne concentration of viable microorganisms in the influent and effluent airstreams using microbial assay methods.

Figure 13: Efficiency Against SARS Coronavirus Bioaerosol

Sampling Time (min)	Positive Control (total TCID50* units)	Respirator Media (total TCID50 units)		
15	3×10^3	BDL	BDL	BDL
60	3×10^4	BDL	BDL	BDL
120	1.5×10^5	BDL	BDL	BDL

BDL = Below detection limit

The date generated in Figure 13 is from an aerosol generated from a virus stock containing 10E9 TCID50/mL. All values refer to approximate titers established by TCID50. TCID50 is performed by looking at three duplicates (total of 6) of each sample diluted 1:10 from undiluted to the 10E-7 dilution.

The respirator media was shown to provide exceptional resistance to the penetration of live SARS Coronavirus through the media.

MS2 Coli Phage Filtration Efficiency

An evaluation of Viral Filtration Efficiency (VFE) was completed on 47mm diameter swatches of Triosyn-treated respirator filter membranes. [7] This study was audited by a representative from the Pasteur Institute. In this study MS2 coli phage, a surrogate to Venezuelan Equine Encephalitis (VEE) virus was used. It is also a commonly accepted model for aerosol studies. Host Escherichia coli (ATCC 15597) that was used for the plaque assay.

The viral suspension was nebulized in the aerosolization chamber at a temperature between 15°C and 25°C at a flow rate of 5.4LPM. This rate was used in order to correspond to the NIOSH recommended flow rate for individual protection. Figures 14 and 15 demonstrate the penetration of the MS2 coliphage through the samples of Triosyn treated filtration media relative to a positive control. Ten samples of the respirator filtration media were evaluated as part of this experiment.

Figure 14: Samples 1-5

Sampling Time (h)	Positive Control (Total PFU)	Sample 1 (Total PFU)	Sample 2 (Total PFU)	Sample 3 (Total PFU)	Sample 4 (Total PFU)	Sample 5 (Total PFU)
0.5	8.04E+06	1.33E+01	<1.33E+01	1.33E+01	2.67E+01	6.67E+01
1	2.92E+07	<1.33E+01	2.67E=01	2.67E+01	2.67E+01	1.33E+01
2	4.20E+07	5.33E+01	6.67E+01	5.33E+01	1.20E+02	3.33E+02
3	4.20E+07	4.00E+01	2.67E+01	4.00E+01	2.67E+01	2.53E+02
4	1.80E+07	N/A	1.33E+01	N/A	4.00E+01	N/A
5	2.64E+07	1.20E+02	1.73E+02	<1.33E+01	1.20E+02	2.80E+02
6	1.56E+07	1.60E+02	4.00E+01	1.33E+01	9.33E+01	3.20E+02
7	8.56E+07	1.20E+02	1.73E+02	5.33E+01	2.67E+01	3.73E+02
8	3.96E+07	4.00E+01	4.00E+01	2.67E+01	4.00E+01	9.33E+01
Average	3.40E+07	6.83E+01	6.22E+01	2.83E+01	5.78E+01	2.17E+02
% Reduction		99.9997%	99.9998%	99.9999%	99.9998%	99.9992%
Respirator Average	6.17E+01					
Average % Reduction	99.9998%					

Detection Limit: 13.3PFU

Figure 15: Samples 6-10

Sampling Time (h)	Positive Control (Total PFU)	Sample 6 (Total PFU)	Sample 7 (Total PFU)	Sample 8 (Total PFU)	Sample 9 (Total PFU)	Sample 10 (Total PFU)
0.5	8.04E+06	<1.33E+01	2.67E+01	4.00E+01	2.53E+02	<1.33E+01
1	2.92E+07	5.33E+01	1.33E+01	4.00E+01	2.67E+01	<1/33E+01
2	4.20E+07	2.67E+01	<1.33E+01	<1.33E+01	2.67E+01	2.67E+01
3	4.20E+07	N/A	8.00E+01	N/A	N/A	<1.33E+01
4	1.80E+07	N/A	N/A	N/A	N/A	N/A
5	2.64E+07	1.33E+01	2.67E+01	8.00E+01	1.33E+01	2.67E+01
6	1.56E+07	<1.33E+01	1.33E+01	5.33E+01	1.33E+01	1.33E+01
7	8.56E+07	5.33E+01	8.00E+01	6.67E+01	9.33E+01	6.67E+01
8	3.96E+07	<1.33E+01	<1.33E+01	5.33E+01	5.33E+01	<1.33E+01
Average	3.40E+07	2.10E+01	3.00E+01	4.76E+01	6.86E+01	1.67E+01
% Reduction		99.9995%	99.9995%	99.9998%	99.9995%	99.9996%
Respirator Average	6.17E+01					
Average % Reduction	99.9998%					

Detection Limit: 13.3PFU

Swatches of filtering material from the Triosyn-treated respirators allow penetration levels between <13 (below the experimental detection limit) and 3.73 x 10^2 total PFU per sampling point when subjected to a bioaerosol challenge containing an average of 3.40 x 10^7 total PFU of MS2 coli phage per sampling point. The combined average penetration level over the 8-hour test for all ten samples tested is 6.17 x 10^1 total PFU per sampling point. This shows that the Triosyn treated respirator filtration media prevents the average penetration of 99.9998% of aerosolized MS 2 coli phage.

U.S. Air Force Testing Using MS2 Coli Phage

Testing was conducted by the Air Force Research Laboratory at Tyndall AFB in which both respirators and swatches of the filtration media were subjected to a bioaerosol of MS2 coli phage. Commercial off-the-shelf respirators were also evaluated in this study.[8]

Respirator samples were sealed to an empty canister with a bead of hot melt glue. The integrity of the seal was not tested. Each canister bearing a mask was sealed to the underside of a Plexiglas plate, which was then seated on a rubber gasket and bolted into a sampling port. This configuration placed the external face of the mask in contact with the aerosol and caused air from the sampling plenum to flow in through the face.

MS2 Coli phage (ATCC 15597-B1) stock was diluted to ~2x10^8 PFU/mL in sterile water and delivered to three six-jet Collison nebulizers. Compressed air (20psi) was fed into the nebulizers to deliver a uniform microorganism-air aerosol. The total challenge time for each test article was 6 hours; after each hour of challenge the impingers were collected and replaced with a fresh set.A standard plaque assay was used to determine phage concentrations of the samples and the positive control. Samples were tested in duplicate with product A samples being labeled as C-A1 and C-A2 and product B samples labeled as C-B1 and C-B2.

Figure 16: Performance of commercial N95 respirators against MS2 Coli phage

Hours	Challenge	C-A1 Count Reduction	% Reduction	C-A2 Count Reduction	% Reduction	C-B1 Count Reduction	% Reduction	C-B2 Count Reduction	% Reduction
1	1.02E+08	1.02E+06	99.00%	1.94E+06	98.09%	4.23E+05	99.58%	1.80E+05	99.82%
2	9.63E+07	1.29E+06	98.66%	1.46E+06	98.49%	1.98E+05	99.79%	2.61E+05	99.73%
3	9.36E+07	2.88E+06	96.92%	1.55E+06	98.35%	4.41E+05	99.53%	3.15E+05	99.66%
4	5.04E+07	1.59E+06	96.84%	1.04E+06	97.95%	6.03E+05	98.80%	3.69E+05	99.27%
5	8.91E+07	2.66E+06	97.02%	5.40E+05	99.39%	6.84E+05	99.23%	2.52E+05	99.72%
6	6.21E+07	1.20E+06	98.07%	8.28E+05	98.67%	4.86E+05	99.22%	3.24E+05	99.48%
Total	4.93E+08	1.06E+07	97.84%	7.35E+06	98.51%	2.84E+06	99.43%	1.70E+06	99.66%

From the data in Figure 16 both commercial masks tested can seen to exclude more than the rated 95% of the bioaerosol challenge. Absent a classification of the particle sizes we cannot speculate on the significance of this observation.

Figures 17 and 18 provide the results from the evaluation of 7 samples (T-1 through T-7) of the Triosyn-treated respirators using the same methodology which was used for the evaluation of the commercial respirators in Figure 16.

Figure 17: Performance of Triosyn treated respirators against MS2 Coli Phage– part 1

Hours	Challenge	T-1 Count Reduction	% Reduction	T-2 Count Reduction	%Reduction	T-3 Count Reduction	% Reduction
1	4.32E+06	7.23E+03	99.9833%	3.92E+04	99.9094%	2.70E+02	99.9994%
2	2.50E+06	1.79E+04	99.9203%	7.54E+04	99.6649%	9.00E+01	99.9994%
3	2.61E+07	6.60E+03	99.9747%	1.99E+04	99.9239%	9.00E+01	99.9997%
4	7.92E+07	7.08E+03	99.9911%	1.64E+04	99.9792%	1.80E+02	99.9998%
5	1.04E+08	7.65E+03	99.9926%	6.39E+04	99.9383%	3.00E+02	99.9997%
6	1.29E+08	1.31E+04	99.9898%	5.31E+04	99.9587%	4.80E+02	99.9996%
Total	4.03E+08	5.96E+04	99.9852%	3.68E+05	99.9336%*	1.41E+03	99.9997%

* Sample T-2 was rejected at 99% confidence level as an outlier.

Figure 18: Performance of Triosyn treated respirators against MS2 Coli Phage– part 2

Hours	Challenge	T-4 Count Reduction	% Reduction	T-5 Count Reduction	% Reduction	T-6 Count Reduction	% Reduction	T-7 Count Reduction	% Reduction
1	6.66E+07	3.84E+03	99.9942%	3.90E+02	99.9994%	3.42E+03	99.9949%	5.22E+03	99.9220%
2	5.80E+07	2.25E+03	99.9960%	1.50E+02	99.9997%	1.92E+03	99.9966%	5.91E+03	99.9894%
3	7.29E+07	3.33E+03	99.9954%	3.00E+02	99.9996%	4.86E+03	99.9933%	3.30E+03	99.9955%
4	6.30E+07	3.21E+03	99.9949%	5.10E+02	99.9992%	2.91E+03	99.9954%	4.17E+03	99.9934%
5	7.56E+07	3.27E+03	99.9957%	3.30E+02	99.9996%	4.20E+03	99.9944%	4.41E+03	99.9942%
6	1.04E+08	4.50E+03	99.9957%	2.10E+02	99.9998%	4.26E+03	99.9959%	3.09E+03	99.9970%
Total	4.03E+08	2.04E+04	99.9953%	1.89E+02	99.9996%	2.16E+04	99.9951%	2.61E+04	99.9940%

Under the test conditions, the Triosyn polymer incorporated into the test system decreased the rate of penetration of viable viral particles by a factor of approximately 10^2. The Triosyn polymer was found to be accurately classified as a reactive material, as understood in the context of protective equipment and gear. The Triosyn-treated respirators have also been shown to outperform commercial N95 respirators on the market in terms of preventing live viruses from passing through the filtration.

IV. Bacterial Filtration Efficiency

Staphylococcus *aureus*

Testing was performed by Nelson Laboratories on several respirators and a mask to evaluate their performance against a bioaerosol of Staphylococcus *aureus*.[10] The test was completed using ASTM F2101. This test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials. An approximately three inch diameter area was tested on the outside surface of the samples.

Figure 19 shows the bacterial filtration efficiency of the Triosyn-treated filter compared with 2 N95 respirators (3M 8210 and Willston Saf-T-Fit 14110321) and with a dust mask.

Figure 19: Bacterial Filtration Efficiency against Staphylococcus *aureus*

Sample	Triosyn -treated filter	3M 8210 (N95)	Willston Saf-T-Fit 14110321 (N95)	Degil Dust Mask
1	>99.%*	>99.%*	>99.%	43%
2	>99.%*	>99.%*	>99.%*	64%
3	>99.%*	>99.%*	>99.%*	57%
4	>99.%*	>99.%*	>99.%*	68%
5	>99.%*	>99.%*	>99.%*	46%
Control Average: 2147 CFU				
Mean Particle Size (MPS): 3.0 µm				

* The maximum filtration efficiency that can be determined by this method is 99.9%.

The Triosyn treated respirators tested were shown to provide equivalent bacterial filtration to N95 respirators on the market today and significantly improved performance over the dust mask tested and comparable results with the N95 respirators evaluated.

V. Face Fit and Total Inward Leakage Performance

In a study published by Dr. Warren R. Meyers, West Virginia University, the T-5000 series respirators were compared to other respirators on the market for face fit and total inward leakage. [11]

Leading brands of respirators manufactured for use in the United States were evaluated on the Los Alamos National Laboratories (LANL) 25 person, half face piece fit test panel. The various members of the testing panel have a combination of face and lip lengths.

Evaluations involved making simultaneous Fit Test (FT) and Total Inward Leakage (TIL) measurements on each member of the panel for each of the twelve brands of respirators.
Figure 20 shows a sample of the data generated from the testing.

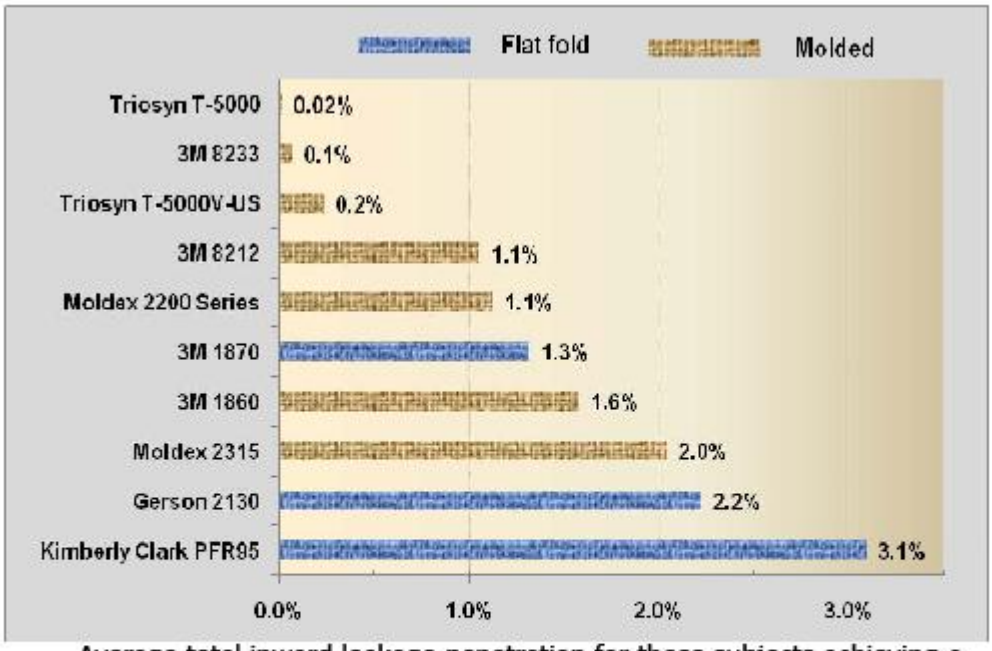
Figure 20: Total Inward Leakage (TIL) Data for Respirators Currently on the Market

Face	T-5000V PF for TIL	T-5000V TIL	3M-1870 PF for TIL	3M-1870 TIL	3M-1860 PF for TIL	3M-1860 TIL
1	2247	0.0%	61	1.6%	91	1.1%
2	160	0.6%	115	0.9%	85	1.2%
3	8131	0.0%	172	0.6%	93	1.1%
4	8781	0.0%	96	1.0%	145	0.7%
5	11914	0.0%	15	6.7%	58	1.7%
6	3914	0.0%	56	1.8%	86	1.2%
7	4392	0.0%	41	2.4%	82	1.2%
8	24077	0.0%	50	2.0%	118	0.8%
9	11863	0.0%	101	1.0%	67	1.5%
10	3166	2.2%	63	1.6%	23	4.3%
11	45	0.0%	77	1.3%	26	3.8%
12	2802	0.0%	116	0.9%	31	3.2%
13	11348	0.0%	141	0.7%	67	1.5%
14	8628	0.0%	13	7.7%	20	5.0%
15	11073	0.0%	55	1.8%	22	4.5%
16	16032	0.0%	50	2.0%	51	2.0%
17	10231	0.0%	134	0.7%	64	1.6%
18	8306	0.0%	129	0.8%	68	1.5%
19	4084	0.0%	135	0.7%	41	2.4%
20	4508	0.0%	95	1.1%	39	2.6%
21	1587	0.1%	98	1.0%	72	1.4%
22	11466	0.0%	108	0.9%	75	1.3%
23	48	2.1%	91	1.1%	47	2.1%
24	6801	0.0%	80	1.3%	38	2.6%
25	4248	0.0%	111	0.9%		-
TIL Avg.		0.2%		1.7%		2.1%

* PF is not the same as FF and should not be used as a comparison for Fit Factor.

PF values above are used only to calculate TIL

Figure 21: Total Inward Leakage Comparison for Various Respirator Models



Source: Comparative Analysis of U.S. Medical and Emergency Response Disposable Respirators, Warren R. Myers Ph.D., M.P.H., C.I.H., Respirator Consultations, Oct 2007

The T-5000 series respirators were also shown to provide significantly better inward leakage performance (less inward leakage) than N95 respirators currently on the market.

The T-5000 series were the only respirators shown to fit all 25 face shapes and sizes tested. The probability of successfully passing a fit test, after achieving a good fit check, was approximately 95% for the T-5000 and T-5000V respirators. This result was significantly better than most of the respirators tested.

VI. Fluid resistance to splashes and sprays

Laboratory testing was completed by Nelson Laboratories, an independent testing laboratory, in accordance with ASTM F 1862.[12] This test method is used to evaluate the resistance of medical face masks to penetration by the impact of a small volume (~2 mL) of a high velocity stream of synthetic blood. The samples were conditioned at 21 ±5°C and a relative humidity of 85 ±5% for a period of at least 4 hours prior to testing. Figure 22 shows the incidence of penetration when 10 samples of a number of commercial respirators, including the T-5000 respirator, were exposed to the high velocity stream of synthetic blood.

Figure 22: Synthetic Blood Resistance for NIOSH approved respirators

	Model & corresponding NIOSH rating									
Sample	T-5000 P95	3M 1860 N95	3M1870 N95	3M 8212 N95	MX 2200 N95	AP 695 N95	FA 2130 N95	KC PFR95 N95	MX 2315 N99	3M 8233 N100
1	None Seen	None Seen	None Seen	Yes	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen
2	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen
3	None Seen	None Seen	None Seen	Yes	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen
4	None Seen	None Seen	None Seen	Yes	Yes	None Seen	None Seen	None Seen	None Seen	None Seen
5	None Seen	None Seen	None Seen	Yes	None Seen	Yes	None Seen	None Seen	None Seen	None Seen
6	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen
7	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	Yes	None Seen
8	None Seen	None Seen	None Seen	Yes	None Seen	None Seen	None Seen	Yes	None Seen	None Seen
9	None Seen	None Seen	None Seen	Yes	None Seen	None Seen	None Seen	None Seen	Yes	None Seen
10	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen	None Seen

The data shown above was generated at a pressure of 160mm Hg. Medical face mask pass/fail determinations are based on visual detection of synthetic blood penetration. A number of the N95 and N99 respirators evaluated failed to prevent the penetration of the synthetic blood through the respirator filtration. The synthetic blood did not penetrate the T-5000 respirators during this test.

VII. Regulatory approvals

a. Triosyn resin is registered with the Environmental Protection Agency, U.S. EPA Registration No. 72897-1
b. NIOSH P95 Registration No. TC-84A-4110 (T-5000)
c. NIOSH P95 Registration No. TC-84A-4234 (T-5000V)
d. Health Canada – T5000 series respirators, Class I License No. 1748
e. T-5000 series respirators meet the Nuclear Regulatory Commission (NRC) regulations for their respiratory program. Respirators meetings these requirements must have:
    i. Seal-enhancing rubber or elastomeric material applied to the *entire* face-to-face piece seal area and
    ii. An *adjustable* four-point (minimum) suspension strap system

VIII. Conclusion

The testing presented in this document demonstrates that the Triosyn technology is effective at significantly reducing the concentration of a wide range of pathogens when they are exposed to the Triosyn material. The results from this testing show that the Triosyn-treated filtration media is highly effective at preventing the penetration of both live viruses and bacteria. Included in these pathogens are Avian Flu (H3N2) and the SARS Coronavirus. The T-5000 series respirators are products that can significantly reduce the penetration of a pathogen into the breathing zone of a respirator wearer.

The T-5000 series respirators has been shown to effectively fit different 25 face shapes and sizes. This demonstrates that the respirators will provide a good seal for the vast majority of people. This superior face fit results in superior total inward leakage values when compared to other respirators. The T-5000 respirators have been shown to also provide resistance to splashes and sprays.

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