Triosyn® Disposable Respirators

Frequently Asked Questions

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Rev.10.28.06

Triosyn® Disposable Respirators

FREQUENTLY ASKED QUESTIONS

In 1993, Triosyn Corporation recognized the need for disposable respirators that provided superior filtration efficiency in the face of emerging pathogens, pandemic threats and the possibility of biological attacks. Responding to worldwide demands for specialized high performance, rugged, convenient respiratory filtration, Triosyn created a new type of filtration media, altering the landscape of air stream filtration. The currently available standard N95 respirators provide much higher filtration efficacy than standard surgical masks, but are still inadequate against airborne viruses. Triosyn Research Laboratories married critical technologies to provide a high performance, high value solution that stops ≥ 99.99% of the microorganisms, including viruses, from penetrating through the respirator. This has been demonstrated repeatedly in numerous rigorous independent studies.

We live with the very real probability of airborne infectious threats from many possible natural and manmade sources. It is critical that we understand and are prepared for those risks - not panic, not create doomsday fear – but be prepared.

1. Why are standard N95 respirators inadequate against many airborne biological particles?

There are many contaminants that challenge the respiratory system, including dust, bacteria, fungi and viruses. These particles can range in size from 0.02 microns (µm) to 100 µm, as is illustrated in Figure 1. NIOSH requires that N95 respirators filter out salt particles at 0.3 µm for 20 minutes with a minimum efficiency of 95%. While most dust particles, bacteria and fungi are filtered out by commercially available N95 respirators, viruses fall below the 0.3 µm size of the NIOSH test salt particles and can escape filtration.

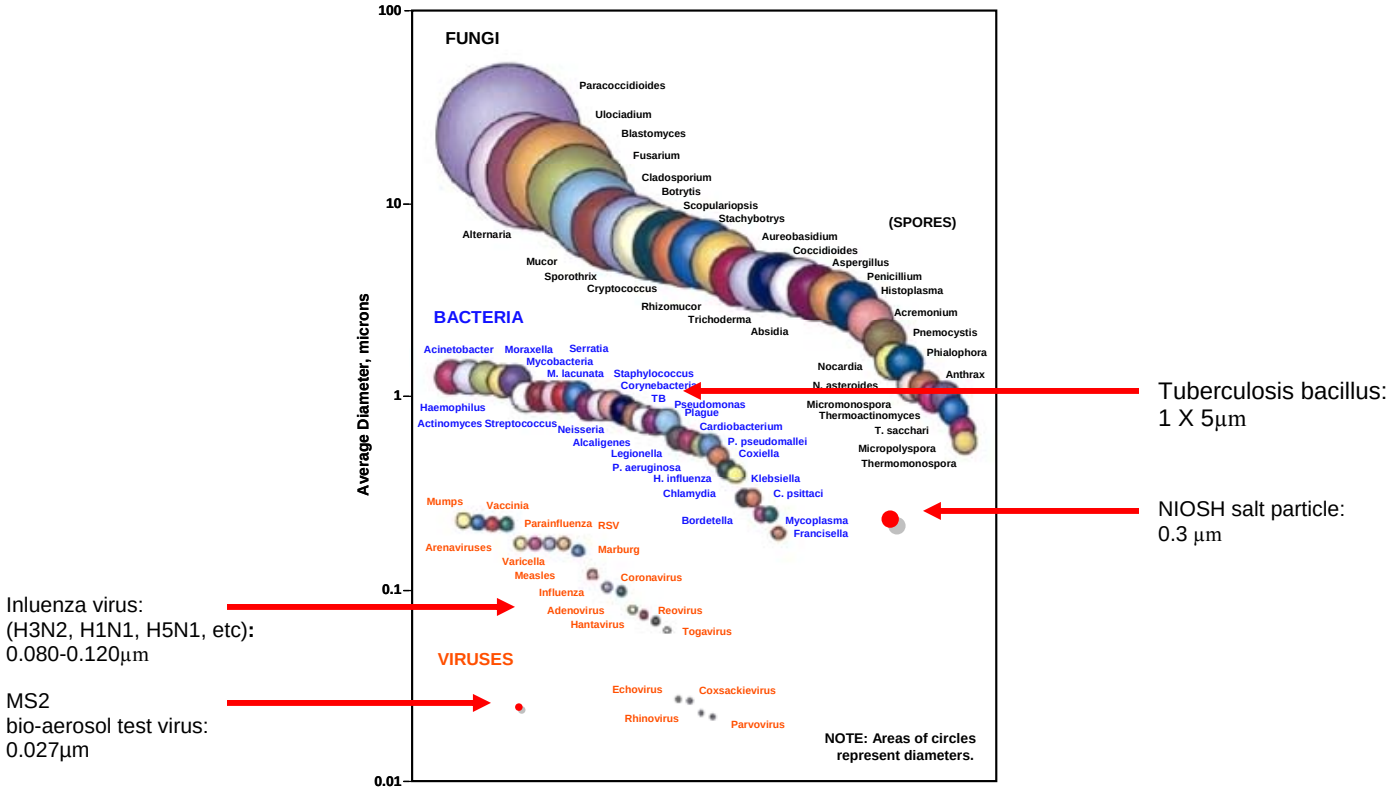


Figure 1. Kowalski and Bahnfleth (1998). Airborne respiratory diseases and mechanical systems for control of microbes. *Heating, Piping, Air Conditioning*. July: 34-48.

2. I thought that 0.3 µm was suppose to be the hardest sized particle to filter out of an air stream.

While around 0.3 µm is the hardest non-biological particle to prevent from penetrating an air filtration device, recent studies have demonstrated that extremely small biological particles, such as viruses, behave differently. Airborne viruses are much more difficult to capture and retain. If respirators or other forms of respiratory protection are to be used when exposure to viruses is anticipated, data from tests using airborne viral challenges should be required – in standards, guidelines and product selection criteria. *Balazy A, et.al.AJIC 2006;34(2):51–57.*

3. How many viruses does it take to cause a respiratory infection?

The number of viruses required to cause infection is referred to as the infectious dose. The infectious dose can be altered by variations in the environment, the health of the individual, the route of exposure and the biological properties of the virus. However, general infectious dose levels have been established in scientific literature for several viruses as displayed in Figure 2.

Viruses Can Be Acquired Airborne Route	Size µm (microns)	Associated Diseases	Infectious Dose No. Viruses (pfu)
Dengue, Ebola & Marburg viruses; Hantavirus; Lassa & Yellow Fever viruses	0.04 – 0.13	Viral hemorrhagic fevers	1 -100
Rubella virus	0.05 – 0.08	Rubella (German measles)	60
Eastern, Western, Venezuelan Equine Encephalomyelitis viruses	0.06 – 0.07	Viral encephalitis	10 -100
Adenovirus	0.07 – 0.09	Respiratory infections, tumors	1 -100
Orthomyxovirus (family of influenza viruses)	0.08 – 0.12	Influenza	1 - 790
Rubeola	0.10 – 0.25	Measles (respirator and CNS of adults)	1
Coronavirus	0.20	Severe Acute Respiratory Syndrome (SARS)	?
Variola virus	0.25 – 0.30	Smallpox	10 -100
Viral infectious dose is usually summarized as:			10 -100 viruses
MS2 Coliphage	0.023-.027	A virus that attacks bacteria. Used as a surrogate in bio-aerosol testing	
Ø X174 Coliphage	0.027	A virus that attacks bacteria. Used as a surrogate in bio-aerosol testing	

Figure 2. References are listed at the end of this document

4. If N95 respirators are inadequate, then why would WHO and CDC recommend them?

NIOSH approved N95 respirators have historically been one of the best disposable respiratory protection devices available. They were originally created for worker protection from industrial dust and particulates, as the requirements of the N95 certification test imply. After years of use in industry, they

were introduced into the healthcare environment to protect caregivers exposed to pulmonary tuberculosis, a highly infectious disease. As tuberculosis bacilli (*Mycobacterium tuberculosis*) measure 1µm - 10 µm, they are effectively filtered by NIOSH approved N95 respirators. Filtration efficiency and the fit of the respirators are important factors as it only requires the inhalation of a few TB bacilli to establish an infection.

Because NIOSH approved N95s respirators have traditionally been effective in TB control, they were recommended by the CDC and WHO for other biological particles such as SARS and avian influenza. However, the NIOSH certification process does not include an evaluation of viral filtration efficiency! Furthermore, recent studies suggest that NIOSH approved respirators do not exclude biological particles less than 0.3µm in size with 95% filtration efficiency as it was historically assumed (*Balazy A, et.al.., AJIC 2006;34(2):51–57*). Today, we face ever increasing threats of new and emerging pathogens, pandemic influenza and bioterrorism. Figure 2 emphasizes that the majority of highly pathogenic viruses are a fraction of the size of the TB bacilli. Respirators depended upon for protection against airborne viral exposure need to be evaluated against challenges of viral aerosols. Because many of these extremely small microbial threats can infect an individual with as few as 1-100 microorganisms, NIOSH approved N95 disposable respirators are inadequate to ensure that the wearer is protected during airborne viral exposures.

5. What are the characteristics of bio-aerosols created by sneezing, coughing and speaking?

An average sneeze (Figure 3) produces about 500,000 droplets, while a cough may produce over 1,000. Even speaking produces a bio-aerosol (Figure 4). As noted in Figure 5, the droplet composition initially propelled from the mouth ranges in size from about 1,000µm to less than 0.5µm with an average of 10µm for all three forms of human production. However, these droplets rapidly evaporate to their core nuclei ("naked" microorganisms) as displayed in Figure 5. This is significant as it means that a large proportion of the initial propelled droplets will rapidly evaporate to the microorganisms they contain. These nuclei, as they are referred to, can stay suspended in the air currents for long period, travel long distances, and can be small enough to evade capture by NIOSH approved N95 respirators. Data presented in response to questions following this section demonstrate that even N95 respirators let a significant number of infectious particles pass through the filtration media when challenged with these "naked" viral nuclei.

Figure 3

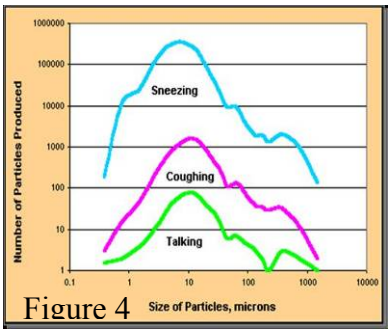


Figure 4

Diameter of Droplet Microns (µm)	Time takes to evaporate to "naked" virus Seconds (s)	Distance droplet will fall before evaporates to naked virus, etc.meters (m)
200	5.2	6.51
100	1.3	0.42
50	0.31	0.025,5
25	0.08	0.001,59
12	0.02	0.000,000,000,84

Figure 5. CB Beggs, PhD, Engineering the Control of Airborne Pathogens 2006 University of Leeds LS2: http://www.efm.leeds.ac.uk/CIVE/MTB/CBB-paper1.pdf.

6. Are there test data comparing Triosyn Respirators to NIOSH approved N95 respirators?

The result of numerous studies, some of which are shown below, demonstrate the enhanced filtration efficiency of Triosyn® Disposable Respirators over other NIOSH approved N95 technologies. No one knows for certain the number of airborne viruses that would be encountered in the event of a pandemic influenza, SARS, bioterrorist attack or even when exposed to a more routine airborne infection such as chicken pox. However, it is has been thought to be below 10,000 plaque forming units (pfu interpreted as the number of viruses) per square meter. Studies often exaggerate the level of viral challenge exposure so that the results can highlight the differences in filtration performance.

The study in Figure 6 was performed using the 0.023µm, MS2 virus, a coliphage internationally used for bio-aerosol testing. This study was performed with a respirator face velocity equivalent to 85 liters per minute (LPM), the same flow rate used by NIOSH to represent the breathing effort during heavy work activity. It should be noted that the NIOSH approved N95 respirators allowed 100 to 10,000 times more MS2 viral particles to penetrate the filtration media than the Triosyn Respirator permitted.

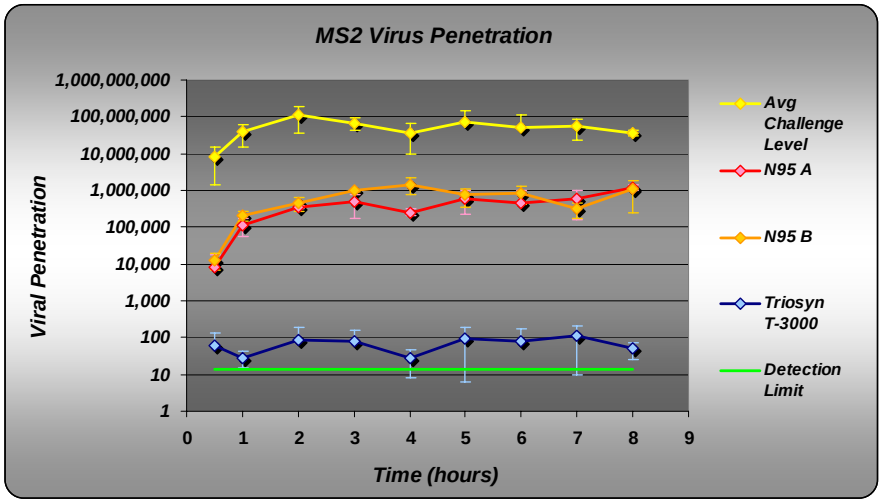


Figure 6. Flow: 85 LPM equivalent – Duration 8 hours
Study M05-0698-0705 Challenge average about 50,000,000 virus particles

Similarly, Figure 7 demonstrates the enhanced filtration performance of the Triosyn® Respirators over commercially available N95 respirators. This MS2 viral penetration study was performed at the Air Force Research Laboratory Protection Branch (MLQF), Tyndall AFB, FL.

Challenge level

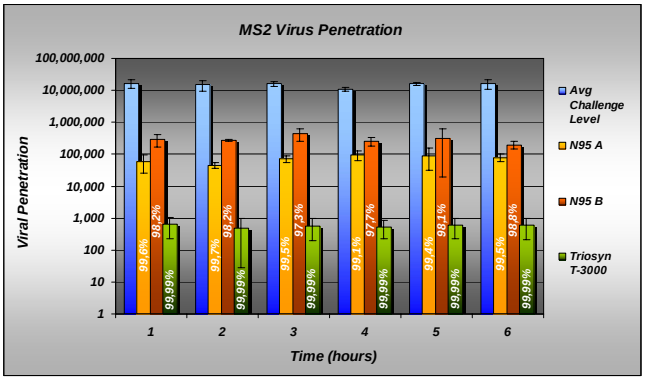


Figure 7. Flow: 85 LPM - Duration: 6 hours

Results of the study shown in Figure 8 demonstrate that as the level of virus particles increases, so does the viral penetration through commercially available N95 disposable respirator media. In contrast, there were no viruses detected passing through the Triosyn Respirators regardless of the increase in challenge exposure.

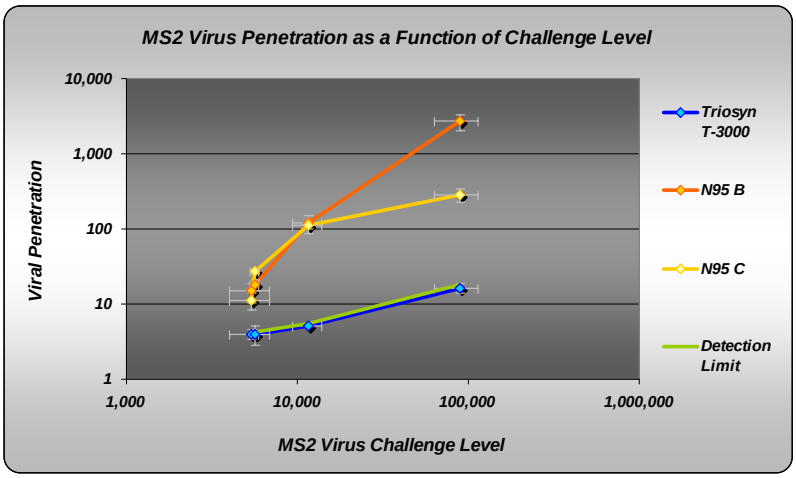


Figure 8. Flow: 85 LPM - Duration: 90 minutes
Study M06-0031.0042.0043.0058

Triosyn® disposable respirators have also been tested against the SARS Coronavirus by independent laboratories as shown in Figure 9. This study utilized levels of SARS viral exposure thought to more closely represent potential indoor airborne exposure.

Testing With SARS Coronavirus

		Triosyn Series Media					
Sample Time (min)	Challenge: Total TCID $Units_{50}$ SARS Coronavirus	Sample 1 (Total $TCID_{50}$ Units)	Sample 2 (Total $TCID_{50}$ Units)	Sample 3 (Total $TCID_{50}$ Units)	Sample 4 (Total $TCID_{50}$ Units)	Sample 5 (Total $TCID_{50}$ Units)	Sample 6 (Total $TCID_{50}$ Units)
15	3,000	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected
60	30,000	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected
120	150,000	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected
Total		No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected	No Virus Detected

Figure 9.
Study Health Canada.4.04 NML No 1.

5. Do Triosyn® Respirators maintain their enhanced performance over extended exposure?

Yes. There are numerous studies comparing the filtration efficiency of the Triosyn respirators to a plethora of commercially available NIOSH approved N95 respirators. The results illustrated in Figure 10, demonstrated that Triosyn respirators consistently provided a much higher level of filtration efficacy over time when challenged with aerosolized MS2 virus. This is in sharp contrast to the performance of the NIOSH approved N95 respirator which started with a lower level of protection than the Triosyn respirators and rapidly deteriorated further from there. It is also important to note the standard deviation (represented by the error bars) shows the wide variation in respirator to respirator performance of this NIOSH approved N95 respirator brand tested compared to the lack of performance variation demonstrated by the Triosyn respirators. The performance of other NIOSH approved N95 disposable respirators may vary.

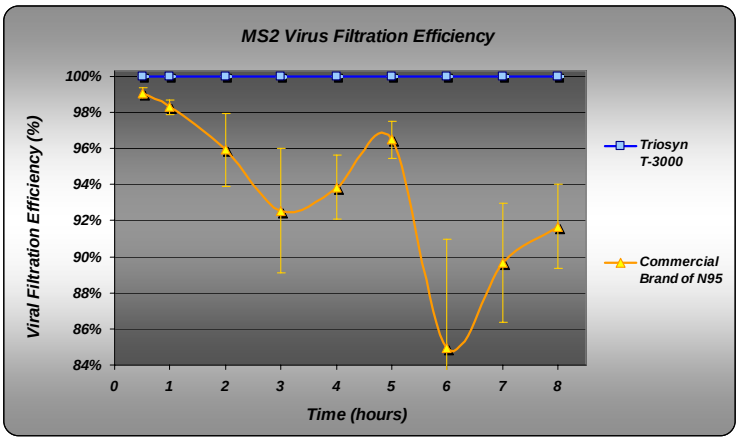


Figure 10. Flow: 85 LPM - Duration: 8 hours
Study M05-0699/0702

The study presented in Figure 11, shows the results of a continuous challenge of approximately 5,000 viral particles per hour over a 24 hours period. Needless to say, wearing a respirator for 24 hours is not a realistic scenario, however it does help to further emphasize the difference in extended filtration performance between Triosyn respirators and two commercially available NIOSH approved N95 respirators.

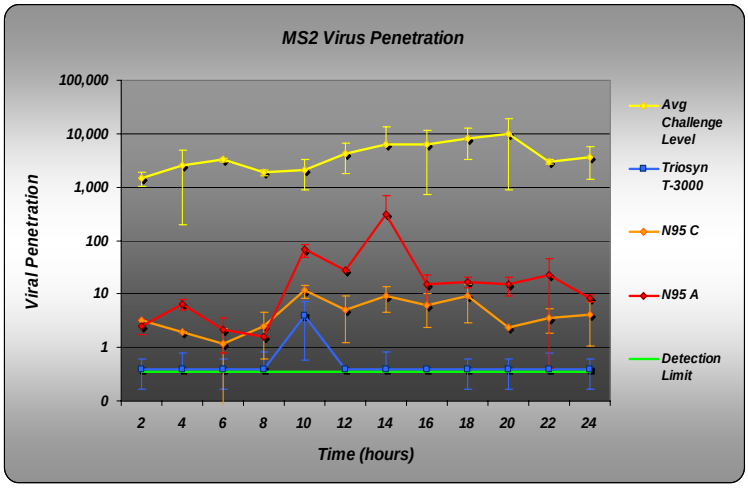


Figure 11. Flow: 85 LPM - Duration: 24 hours
Study M05-0702 & M05-0704

6. What labs have tested the Triosyn technology?

For the past 13 years, the Triosyn Corp.'s R&D Team has collaborated with the following world renowned independent testing laboratories, governmental entities and military institutions to create and design leading edge technologies and/or perform evaluative testing protocols. Laboratories include:

- AppTec ATS Laboratory
- ATS Laboratories
- Battelle: CBIAC
- Bodycote
- Canadian Science Center for Human and Animal health
- Center for Applied Microbiology & Research (CAMR)
- DTRA Laboratories
- Center for Research on Environmental Microbiology (CREM), University of Ottawa
- ESG international
- HARLAN Associates
- Health Canada
- McGill University Laboratories
- Nelson Laboratories
- North American Science Associates (NAMSA)
- Product Safety Laboratory (PSL)
- SafePharm Laboratories
- Springborn Laboratories
- TNO Prins Maurits Laboratory (TNO: The Netherlands Organization)
- Various US Military departments

7. What is Triosyn® Resin and why is it incorporated into the respirator media?

Triosyn® Resin is an innovative, patented, iodinated resin (Figure 12) registered with the EPA. It is incorporated in the Triosyn® disposable respirators to preserve the filter media and thereby prevent the degradation of the media properties under normal conditions of use over many hours. Triosyn interacts with viruses, bacteria, protozoa and fungi through a demand-release mechanism activated by the presence, type and population density of the microorganisms. Triosyn resin incorporates a complex iodine molecule that releases molecular iodine only when in close proximity with microorganisms. This prevents growth, replication and migration of respirator-captured microorganisms. Triosyn also preserves the electrostatic charge on the filtration fibers of the respirator, maintaining the effectiveness of the capture and retention of microbial threats over extended periods of time.

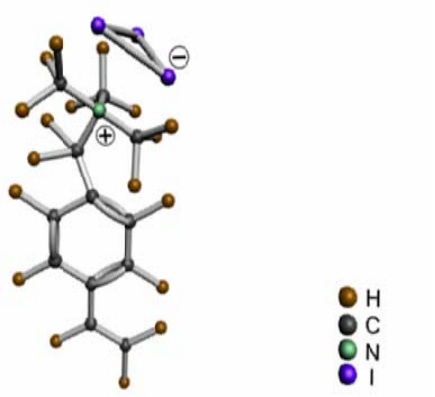
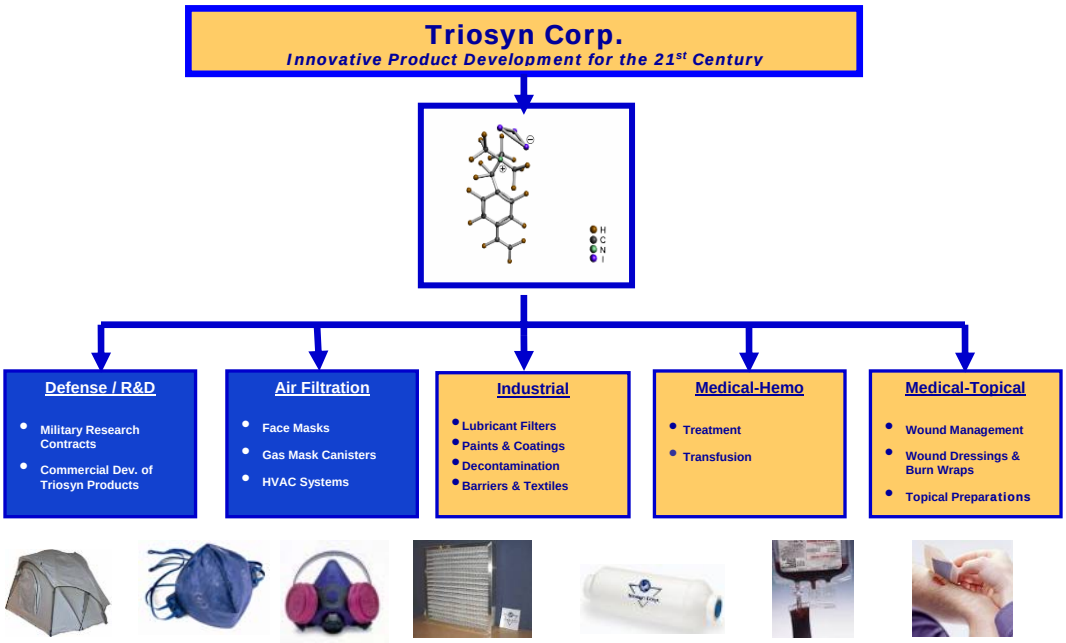


Figure 12.

Upon contact with the media, the microorganisms activate the Triosyn demand-release mechanism. An increased concentration of microorganisms results in a larger number of Triosyn resin sites simultaneously releasing molecular iodine. The molecular iodine then oxidizes the microorganisms, devitalizing them so they can no longer function, grow or reproduce. The release mechanism, along with the inherent properties of the I_2 molecule, combines the broad spectrum activity of I_2 with very rapid effectiveness. When the source of iodine demand is eliminated the Triosyn resin immediately returns to its resting state, preserving its iodine content until reactivated.

8. Has the Triosyn Technology been incorporated into other products?



9. Against which microorganisms has the effectiveness of the Triosyn Technology been tested?

Triosyn Products have been tested against the following:

Viruses	Bacteria	Sporulating Bacteria	Fungi	Protozoa
Φx174 Coliphage **Human Immuno. Virus (HIV)** **MS2 Coliphage** **Newcastle Disease Virus** **Poliovirus Type 1** **Rotavirus SA-11** **SARS coronavirus (Toronto strain)**	***Brucella abortus*** ***Enterobacter aerogenes*** ***Enterococcus faecalis*** ***Erwinia herbicola*** ***Francisella tularensis*** ***Klebsiella pneumoniae*** ***Klebsiella terrigena*** ***Legionella sp.*** ***Micrococcus luteus*** ***Drug Resis. Staph. aureus (MRSA)*** ***Proteus mirabilis*** ***Pseudomonas aeruginosa*** ***Pseudomonas pseudomallei*** ***Salmonella sp.*** ***Serratia marcescens*** ***Shigella flexneri*** ***Staphylococcus aureus*** ***Staphylococcus epidermidis***	***Bacillus anthracis*** ***Bacillus atrophaeus (BG)*** ***Bacillus subtilis***	***Aureobasidium pullulans*** ***Aspergillus niger*** ***Candida albicans*** ***Cladosporium herbarum*** ***Penicillium citrinum*** ***Penicillium sp.*** ***Rhodotorula rubra*** ***Trichophyton mentagrophytes***	***Cryptosporidium parvum*** ***Giardia lamblia*** ***Giardia muris***

Microoganisms tested against Triosyn Air Filtration or Antimicrobial Finishes

Viruses	Bacteria	Sporulating Bacteria	Fungi
Φx174 Coliphage	***Erwinia herbicola***	***Bacillus atrophaeus (BG)***	***Aspergillus niger***
MS2 Coliphage	***Escherichia coli***	***Bacillus subtilis***	***Candida albicans***
Newcastle Disease Virus	***Klebsiella pneumoniae***		***Cladosporium herbarum***
SARS coronavirus (Toronto strain)	***Klebsiella terrigena***		***Rhodotorula rubra***
	Micrococcus luteus		***Trichophyton mentagrophytes***
Avian Influenza reassortant (H3N2)	***Staphylococcus aureus***		
Influenza (H1N1, H3N2, H5N1)	***Staphylococcus epidermidis***		

Figure 13.

10. How is the Triosyn® Technology incorporated into the respirator media?

The Triosyn iodine-activated resin is incorporated into a filtration layer within the respirator where it enhances filtration efficiency and maintains the consistency throughout the use of the respirator. The diagram in Figure 14, illustrates the multi-component media technology system unique to Triosyn® disposable respirators.

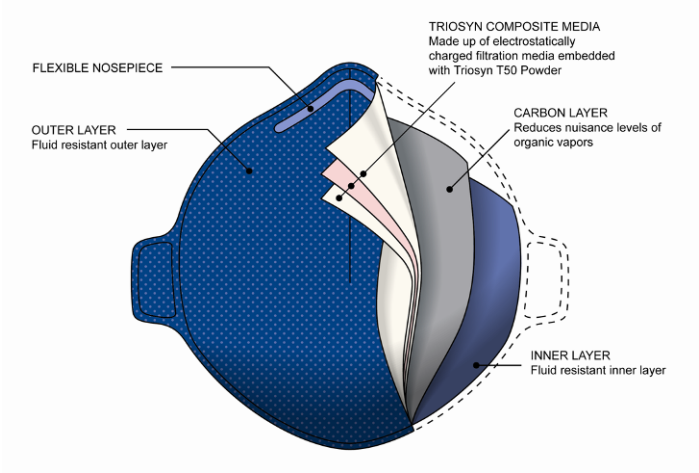


Figure 14.

11. What are the benefits of the carbon layer?

A carbon layer is incorporated in the filtration media to provide a means of reducing nuisance organic vapors and odors. This is a novel and significant advantage for individuals working in disaster zones and other areas where respiratory protection is recommended.

12. How long can the respirator be stored?

Kept sealed in their individual packages, Triosyn® Disposable Respirators have a shelf life of 5 years.

13. How well do Triosyn® Disposable Respirators fit the wearer?

Triosyn® Disposable Respirators were tested with regard to fit along with a leading commercially available NIOSH approved N95 respirator by an independent Fit Testing Laboratory. Testing was performed using the standard OSHA protocol on a test panel of 25 persons. Fit testing was assessed for each respirator model on each test subject. The tests demonstrated that Triosyn® disposable respirators not only meet the OSHA Fit Test standards requirements but also exceeds the fit factors of the leading commercially available disposable respirator.



14. Are Triosyn® Disposable Respirators used by First Responders?

Triosyn respirators are used by many First Responders both nationally and internationally. All three Triosyn® Disposable Respirator models – Triosyn T-3000, Triosyn T-5000 and Triosyn T-5000V – are on the Approved Equipment List (AEL) for Personal Protective Equipment (PPE) in the Department of Homeland Security's Responder Knowledge Base Program (RKB). The RKB is a web-based objective information service for the emergency responder community funded by the DHS and used by over 40,000 State and Federal subscribers. www.rkb.mipt.org

15. What is known about iodine allergies?

Iodine allergies have been purported to result from hypersensitivity reactions to iodinated drugs or consumption of seafood. Hypersensitivity reactions to iodinated drugs are rare and most of the literature reported cases investigating this issue are unable to establish a direct causal relationship linking iodine as the responsible chemical for these reactions. For example, based on the literature review by *Dewachter et al (2005)*, povidone, and not iodine, is probably the compound responsible for allergic reactions to the skin antiseptic povidone iodine. The same is true in the case of allergic reactions to iodinated contrast media, where the iodine atom has not been shown to be the allergenic determinant responsible for these reactions.

Likewise, it is also common to associate allergy to seafood with allergy to iodine. However, it appears that protein M or tropomyosin are the allergens responsible for patient sensitization involving fish and shellfish allergies (Dewachter et al, 2005) and not the iodine molecule itself.

In summary, it appears that the term "iodine allergy" is a misnomer commonly used in the medical field, since it does not correspond to an identified clinical entity. Thus, asking a patient if he/she is allergic to iodine is a question that should be avoided because the question is not relevant. It is important to separate the chemical element "iodine" from the molecule which contains it; given that it is not iodine in itself which provokes the allergic reaction, but the carrier molecule or solution. It is also important to note that salt iodization is a worldwide recognized procedure to prevent iodine deficiency disorders. However, there has been negligible evidence of any adverse effects, such as allergic reactions, associated with iodine intake (WHO, UNICEF, ICCIDD, 1996).

A summary of the research literature available on the incidence of hypersensitivity reactions to iodine is presented in Figure 15.

Summary of literature research findings on the Incidence of hypersensitivity reactions to iodine:

Literature Reference	Population/location	Period of time	Findings
Dewachter et al., 2005	Review of the literature on "iodine allergy"	Database search from 1967-2004	Implication of iodine has NEVER been demonstrated during allergic hypersensitivity reactions due to iodinated drugs
Cited in Kapil et al, 2003	20,000 children/USA suffering from allergy	1935-1974	Not a single case reported of allergic hypersensitivity to iodine in food
Cited in Kapil et al, 2003	N/A (response to a request for notification of allergy to iodine)	1974--1980	Not a single case reported during this period of time

Figure 15. Additional references: Brown & Mutter, 2003; Dewachter & Mouton-Faivre, 2005; Sato et al., 2004; van Ketel & van den Berg, 1990

16. What is the cost effectiveness of this technology?

When evaluating criteria for selecting personal protective equipments such as a respirator and looking at cost, it is important to examine what you are paying for. Will it be effective in preventing the penetration of airborne biological particles including viruses? Will it maintain a high level of filtration efficacy during the entire use period?

When making purchasing decisions for respiratory protective equipment, the points listed below should be considered. If it is worth buying a respirator, then make certain it provides the level of filtration efficiency that is needed throughout the time the respirator is worn.

A disposable respirator must provide:

- Proof of ≥ 99.99% penetration resistance against airborne biological particles including viruses (Require the test data)
- An active preservative or other means of capture preservation incorporated into the respirator (e.g. Triosyn) to ensure consistent high level filtration efficiency over normal and extended use
- Proof of fluid resistance certification to prevent the passage of microorganisms if struck with bodily fluids including blood or sputum, and other liquids used in the course of activities including water.
- Proof of oil non-penetration certification (exposure to oils, fats, diesel mists, etc., degrade the filtration efficacy of respirators that do not have this property)
- Reduction of nuisance fumes, odors and vapors if such exposure is anticipated
- An excellent fit therein minimizing any face seal leakage
- Comfortable use with low breathing resistance during an extended use period
- Ready personal availability in protected package for immediate protection when emergency arises (cost is too much if the respirator is not readily available when needed)
- Rugged construction that will maintain filtration integrity during expected in-use activities should bio-threat occur

Triosyn® Disposable Respirators provide these critical features making them very cost effective for the value.

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