Fact vs. Fiction: Continuously Active Antimicrobial Coatings

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Abstract

There has long been a need for a solution that continuously reduces the number of bacteria living on surfaces in between cleanings. While many solutions have been proposed, most fall short of delivering on the promise due to efficacy, durability, compatibility, safety, or economical limitations.

The COVID-19 pandemic has heightened the urgency of this need. Unfortunately, many companies are taking advantage of this urgency and marketing various continuously active surface coatings, making unsubstantiated claims that are unapproved by the appropriate regulatory agencies.

This article reviews the contributing factors to the variability in claims on these products and outlines the features to evaluate while deciding on a continuously active antimicrobial coating.

The Need

The role of contaminated surfaces in the transmission of infections to humans has been well studied and well documented (Boone and Gerba, 2007; Weber, Rutala, and Sickbert-Bennett, *Outbreaks Associated with Contaminated Antiseptics and Disinfectants*, 2007; Weber, Rutala, Miller, Huslage, and Sickbert-Bennett, 2010). With the arrival of the COVID-19 pandemic, the Environmental Protection Agency (EPA) has published a list (List N) of momentary disinfectant products deemed effective against the SARS-CoV-2 virus (United States Environmental Protection Agency, 2020). These products provide effective remediation of a contaminated surface. However, they are only effective at the time of application; they are momentary solutions. The surface can get recontaminated immediately, remaining a potential source of infection transmission until the next cleaning episode. Disinfection is a momentary solution, while contamination is a continuous risk.

In response to the pandemic, many organizations have increased the frequency of disinfecting their facilities. However, this strategy is impractical and unsustainable. Instead, they need to find a way to continuously reduce the number of bacteria living on the surfaces in their spaces. Three technologies promise this solution: continuous high-intensity blue light, select active metal plating, and continuously active antimicrobial coatings.

Continuous high-intensity visible blue light with a peak output of 405 nm has been suggested as a potential continuous decontamination solution (Rutala, et al., 2018; Maclean, et al., 2010). However, the safety of long-term exposure to this technology is in question, since it has been shown to irreversibly change/distort key cellular membrane structures, which disrupts cell function (Ratnayake, Payton, Lakmal, and Karunarathne, 2018).

Selective active metal plating, or the use of copper- or silver-coated surfaces, is another approach, though its effectiveness remains unclear. Copper-impregnated hard surfaces and copper textiles reduced healthcare–associated

infections (HAI) in healthcare settings (Sifri, Burke, and Enfield, 2016). However, the risk of bias was quite high and the study failed to determine whether reduced HAIs could be attributed to the use of copper-containing antimicrobial hard and soft surfaces (Muller, MacDougall, and Lim, 2016). Furthermore, broad replacement or renovation of equipment with copper or silver coatings is impractical and expensive.

A third approach is to apply continuously active antimicrobial coatings, which have been shown to continuously reduce the number of bacteria on surfaces between cleanings. The benefit of antimicrobial coatings was demonstrated in a Clinical Infectious Diseases paper which studied intensive care units treated with a continuously active coating over a year. Live cultures taken throughout the study period resulted in statistically lower numbers of bacteria on treated surfaces. This reduction in bio-burden correlated to a statistically significant 36% reduction of HAIs in treated units (Ellingson, Pogreba-Brown, Gerba, and Elliot, 2019).

Evaluating continuously active antimicrobial coating options

Many companies claim they have a durable coating that continuously works to reduce the number of bacteria on most surfaces. Many also claim these coatings reduce the risk of transmitting an infection from the surface. Unfortunately, these claims are made outside of existing EPA regulations and associated product claims.

Unlike the disinfecting products on the EPA's List N, which have been vetted by the EPA for their performance, durable antimicrobial coatings are currently restricted to a standard microbiostat registration with the EPA, which only allows product claims of inhibiting odor-causing bacteria, mold, and mildew. This title also explicitly excludes any claims regarding food-borne illnesses and disease-causing bacteria. Therefore, these products are only approved for use to prevent odors, staining, or deterioration caused by these select microbes on surfaces, and they cannot claim to improve or protect public health.

Companies That Claim Any Impact On Infectious Pathogens, Including Viruses, Have Not Been Vetted Or Approved By The Epa

Currently, the EPA has not developed standard public health claims for continuously active antimicrobial coatings, and any companies that claim any impact on infectious pathogens, including viruses, have not been vetted or approved by the EPA. Like all antimicrobial products, these coatings' claims are strictly limited to their EPA registration language. Undocumented claims are not vetted or approved by the EPA and are out of compliance with this agency's regulations, despite outside evidence or testing.

Though continuously active antimicrobial coatings have existed for years, there are two key reasons why advanced standard claim sets have not been developed for their product category:

- **Traditional testing methods do not work for evaluating new technologies.** Standard EPA methods for measuring the efficacy of disinfectants are intended for momentary cleaning products. They may not accurately assess new technologies that decontaminate in novel ways.
- **The scientific community has not fully explored key issues new technologies may solve**. As new technologies emerge, companies must cooperate with scientific bodies to build a knowledge base against which these products may be assessed, then rapidly assess them. Regarding these coatings, important research is needed on the magnitude of recontamination in a variety of environments which would inform the level of protection a continuously active antimicrobial might need to provide. Also, more research is needed on

the level of constant bacteria reduction that would significantly impact or eliminate public health risk.

- **Regulatory agencies' procedures are not well-equipped to adapt existing frameworks to fit novel technologies.** Regulatory agencies are important agents in developing standardized processes and protocols to govern the deployment of beneficial technologies and regulate false claims. When novel products offer unique value to the market, it can be difficult to find an existing solution among these agencies' processes and protocols. A new level of adaptability and urgency to validate and regulate new technologies will increase the speed with which these products can be brought to market without sacrificing oversight and protections.

The COVID-19 pandemic has elevated the importance of cleanliness and hygiene across industries, leading to significant demand increases and a high level of urgency to provide solutions for clients and customers (Rendle, 2020). The promise of continuously active antimicrobial coatings is an attractive selling point, and product manufacturers and service providers want to respond to this demand. Unfortunately, existing EPA registrations for these products do not allow products to be sold with the promise of inhibiting disease transmission.

While the EPA does not have any formal public health registrations for residual antimicrobials, during a public health emergency, it offers a waiver process to permit the specific use of products that the EPA has vetted and deemed sufficient to address the public health threat. This process requires a consumer to submit a request to use the product to their state agency, which initiates a toxicity and effectiveness review. Upon a successful review by the state, the application is then forwarded to the EPA. They assess the product and determine what claims it can make.

Only One Company Has Been Epa-Approved To Claim Effectiveness Against Coronavirus Over An Extended Period

Very few continuously active antimicrobial coating products have been reviewed through this process, and at the time of publishing, only one has been EPA-approved to claim effectiveness against coronavirus over an extended period (United States Environmental Protection Agency, 2020).

The EPA attempts to enforce action against companies making unsupported claims. The process is reactionary and they may not enact penalties until well after a consumer purchase. Therefore, the purchaser is responsible for validating the claims of any decontamination product they are considering buying, including continuously active antimicrobial coatings.

Here are some ways to assess the validity of continuously active antimicrobial coating product claims:

1. Check the EPA registration of the product to confirm whether they have been authorized to make the claims they are making. Any product vendor that references an EPA registration should be able to share its claims and must abide by them when selling the product. If the product is not registered to make the claims they are directly or indirectly making, the product is not in compliance with EPA regulations and any similar claims made about the product could be subject to EPA action. If the purchaser is still interested in the product, then continue with a deeper vetting.
2. Ask for specific antimicrobial data. Verify the testing reports include:
    1. Results that demonstrate effectiveness against relevant microorganisms (such as human coronavirus).
    2. Results that demonstrate a sufficient rate of kill to reduce the risk of infection due to cross-contamination or transmission. (Rutala and Weber, *Best Practices For Disinfection Of Noncritical Environmental Surfaces And Equipment In Health Care Facilities: A Bundle Approach*, 2019)

    3. Methods that test the product as a dried coating on a surface, not in solution or as a spray. Tests are conducted in solution or when the product is wet are not valid measurements of the residual benefit these products can offer in practice.
    4. Methods that demonstrate that the coating can withstand repeated attacks of the pathogen with continuing decontamination activity. This ensures the product can continuously, effectively fight recontamination.
    5. Methods that demonstrate the coating remains effective after being touched and cleaned. Continuously active antimicrobial coatings are designed to be used alongside daily cleaning in areas that are in use. Confirming effectiveness after wear is extremely important to ensure that the coating will last in occupied spaces.
    6. Methods that measure contamination in a way that is valid to the coating application and not other cleaning mechanisms. Continuously active surface coatings deactivate germs on surfaces, so effectiveness measures should be highly selective to measure live or active germs.
3. Confirm there is a mechanism to measure/control how much coating is on the surface, and whether there is enough coating to provide sufficient antimicrobial benefits in real-world environments. Visual inspection is not enough to ensure these invisible, odorless, non-tacky surface coatings are present on a surface, especially when deployed in high-traffic areas or areas that utilize rigorous cleaning protocols.
4. Review supporting evidence for the durability time frame being proposed. These coatings' durability claims vary widely and can depend largely on how they were tested. This review should include:
    1. Ensuring the product was tested to simulate durability over time. Many of these coatings can remain on surfaces for very long periods if undisturbed. Durability claims should include a mechanism that simulates the wear associated with consistent use and/or cleaning.
    2. Compare these conditions to your facility's usage needs and cleaning schedule. Laboratory methods can vary. The conditions of the durability testing may or may not reflect the type of wear that you would expect in your facility. If a durability claim is supported by a test that does not accurately reflect the wear patterns in your space, you may not expect the coating to last as long as is claimed.
5. Ensure the testing was done in a qualified lab, and/or has been published in peer-reviewed journals. Review the standards of the testing facilities and the rigor with which the results have been validated. Independent testing done by General Laboratory Practice-certified laboratories can support better laboratory practices and standardized protocol use. Also, testing that is accepted for publication in a peer-reviewed journal would ensure the methods, analysis, and conclusions have been assessed by subject matter experts and found to be worth publishing as an addition to academic literature. These indicators of high-quality testing methods and data analysis can differentiate the quality of the testing results that are shared.

Conclusion and Significance

Continuously active antimicrobial coatings have a unique role to play in controlling the spread of infectious bacteria from surfaces to humans. While the EPA has approved one coating through an Emergency Waiver process, it is up to the scientific community to develop protocols to guide the standardized evaluation of these coatings and their ability to deliver on their promise to protect the public from contamination buildup on surfaces.

The suggestions above offer potential building blocks for such protocols. These protocols will support regulatory agencies like the EPA in developing more rigorous standards for this new product category, creating performance thresholds for effectiveness and durability for registration that can validate the claims of these products. Together, these actions enable the broad commercialization of valid products and protect consumers from opportunistic companies making unsupported claims.

Due to the lack of scientifically-established guidelines, it is difficult to differentiate between high and low performers in this category. This is more difficult in the era of COVID-19, as many companies claim to have coatings that deliver health benefits, despite the lack of supporting EPA registration. Because these companies' sales efforts are moving faster than regulatory enforcement actions, it is an industry best practice to request a product's EPA registration label

and clarify its EPA-supported claim language as a part of the vetting and evaluation of any antimicrobial product. This ensures the benefits being claimed are grounded in scientific data and can meet the needs of their facilities.

By considering the criteria above, consumers can make an informed purchase decision and ensure the protection they are being sold is the same protection that they will receive.

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