

## **Raising the Bar on Disinfectant Testing Is It Needed? Experts Disagree**

*By Gail Stout-Flower*

Disinfectants are a standard method for treating non-critical environmental surfaces. Claims of efficacy for any specific pathogen must be tested under laboratory conditions to make sure the formula does what it claims to do. Then, each claim must be reviewed and approved by the EPA before it can be on the product label. This testing must be done per EPA approved standards, which currently require efficacy under a 5 percent organic soil at 200 ppm to 400 ppm hard water.

It seems that testing disinfectant claims under high soil load and very hard water (i.e., “real world” conditions) would be the next logical step to see if a product works under the stresses of existing conditions in situations where surface pre-cleaning may be less controlled. This has been done with one product to date, and surely more will follow. To what extent this type of testing adds to the overall benefits derived by the user is a subject that draws polarized opinions.

### **From the Germ’s Perspective**

Today, the entire globe has been reduced to a simple roadmap. This is good for the global economy and is also a boost for the global transmission of infectious pathogens. One only has to look at the recent epidemics in various global areas of SARS, influenza, monkeypox, avian flu, hoof and mouth disease and illnesses that have caused popular cruise lines to turn back to port, to grasp how fast and thoroughly any disease has the potential to wreak havoc.

Aside from imported diseases, there are plenty to deal with in the U.S. The medical institution recognizes the fact that many are evolving into very antibiotic resistant strains, making them harder to cure.

Ali M. Javadian, PhD, MPH, manager of technology development at Wyeth Vaccines Research in Pearl River, N.Y., is in charge of all technology regarding immunology at that facility. He is adamant about the necessity of infection prevention, saying, “The emphasis must first be on prevention of the spread of infectious diseases and then on the cure.”

### **Disinfection Basics**

In his recent paper, “Surface Disinfection: Should We Do It?”, William A. Rutala, PhD, MPH, Division of Infectious Diseases at the University of North Carolina School of Medicine writes, “Viruses can be acquired from environmental surfaces either directly from surfacet-to-finger-to-mouth or directly from surface-to-mouth.

Chemical disinfection of contaminated environmental surfaces has been shown to interrupt transfer of rhinovirus from these surfaces to hands.<sup>1</sup> In experimental studies, the use of disinfectants has been shown to be an efficient method of inhibiting the transmission of rotavirus to human subjects.”<sup>2</sup>

Loretta Litz Fauerbach, MS, CIC, practice guidance team leader for the Association for Professionals in Infection Control and Epidemiology (APIC), and director of infection control at Shands Hospital, University of Florida in Gainesville, concurs, adding, “Surface disinfection is especially important when the pathogen is spread via the contact route...when a susceptible person is exposed by touching a contaminated object. Not all exposures lead to disease. Some result in contamination of the hands that can then transfer the organism to a susceptible individual if hands are not decontaminated via washing or the use of an alcohol hand gel. In this context surface disinfection becomes important as a reservoir for acquiring the organism, which then can either be transferred via the hands to someone else or infect the person who is directly exposed.”

“Prevention of the spread of infection is paramount no matter what location, global setting, at home, at work or in our leisure settings,” says Paulette Marquardt, RN, central service supervisor at Mayo Clinic Hospital in Phoenix. “The outbreak of disease can be transmitted around the world in an incredibly short time. Objects need to be cleaned to remove all foreign material from the surfaces before disinfection can be accomplished. According to APIC, a disinfectant is a germicide that inactivates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms. Surface disinfectants are used on all environmental surfaces in a hospital setting. This is only one method of preventing the spread of infection. Equally as important to break the chain of transmission is handwashing.”

From a global perspective, Stuart Reid, professor of comparative epidemiology and informatics at the Universities of Glasgow and Strathclyde in Glasgow, U.K., states that disinfectants do play a serious role in the reduction of disease transmission, both directly through biocidal activity and reduced load and also indirectly through general increased standards of hygiene.

Matthew J. Arduino, MS, PhD, supervisory research microbiologist, Epidemiology and Laboratory Branch in the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC) in Atlanta, puts the whole picture into perspective. “What is the actual role of surface disinfecting as related to retarding the spread of bacterial, viral and fungal infectious agents in hospital settings? The answers to these questions must first be prefaced with a short review of the chain of infection. For infection to occur, all five links in the chain must be operational. These links are: a) a susceptible host; b) an agent in sufficient numbers (i.e., dose); c) virulence of the agent; d) mode of transmission; and e) portal of entry.”

“Environmental surfaces may serve as a reservoir of microorganisms,” he adds. Organisms present on these surfaces can be transferred from the surface to a person via hand contact or contact with an object that has touched the environmental surface. This transferal by itself is not enough to result in infection; the organisms must enter the body through a portal of entry (e.g., mouth, eyes, nose, mucous membranes, or break in the skin). Surfaces that are touched frequently by hand during healthcare (e.g., equipment handles and knobs, door knobs, light fixtures and bed rails) are potentially associated with this microbial transfer more frequently compared to that for the floors and walls. Surfaces that do not make contact with the skin of patients, healthcare staff, and visitors (e.g., floors and walls) should be kept clean. Routine disinfection of these surfaces is not warranted, but disinfection may be needed if the surface has been contaminated with a body substance or fluid. Frequently touched surfaces, because of their increased potential involvement with hand-transfer of microorganisms, should be cleaned and disinfected on a regular basis. The purpose of cleaning and disinfecting environmental surfaces is to reduce the numbers of microorganisms on those surfaces. Cleaning and disinfecting helps to eliminate or at least minimize the potential for the surface to serve as a microbial reservoir.”

So experts agree, both stringent cleanliness and the use of disinfectants are deemed effective methods to stem this unseen microbial attack. All disinfectants state that they are to be used on “pre-cleaned” surfaces, because too high an organic soil load reduces the efficacy of these products. So the question becomes, how clean is clean?

### **Taking Disinfectant Testing to the Next Level**

EPA regulations create a fair playing field across all disinfectant products; however, it also allows any company to raise the test level above the standard. The Environmental Protection Agency (EPA) only requires that laboratory testing be proven to the agency’s satisfaction. They will, and have, issued label claims of efficacy under high organic soil-load conditions.

When an animal or human bleeds or issues forth other bodily fluids, these bodily fluids do not self-dilute as they cover a surface. Can cleaning to a 5 percent organic soil level always be enough? One disinfectant manufacturer set out to test their products for efficacy against known pathogens under real world conditions: organic soil load of 98 percent and hard water level of 780 ppm. Their reasoning being that there are circumstances where it would be impossible to know the soil load after pre-cleaning and, therefore, the infectious microbial density in that residual soil.

Robert Prince, president of West Caldwell, N.J.-based Microgen, Inc., a microbiological surface chemical distribution network, says, “We aggressively pursue testing to simulate the most demanding use of conditions for our products

to ensure their effectiveness in actual healthcare situations. Ideally, products should be effective in 100 percent organic soil loads, since the current 5 percent organic soil testing requirement is seldom applicable to real-world situations.”

Microgen’s lab scientists routinely test the company’s disinfectants against a high organic soil challenge of gram negative and gram-positive bacteria as well as enveloped and non-enveloped viruses. “Recently, we completed the successful disinfectant testing of D-125 in 98 percent soil and in 791 ppm hard water against *Salmonella choleraesuis* ATCC 10708 and *Staphylococcus aureus* ATCC 6538. This is the first EPA approval of a disinfectant using such a high organic soil load for testing data.”

Vladis Goncarvos, regulatory affairs manager, Research International, has a positive opinion, saying, “This new claim will probably set a new standard in the industry. Hospitals are going to find this useful in areas where there may be more than just a little dirt. Just because a product is tested at 5 or 10 percent does not mean it won’t work at higher levels of contamination and should be tested. It will raise the bar for disinfectants by providing more confidence. Surfaces are precleaned before being disinfected, but how do they guarantee that the soil remaining on the surface is only 5 or 10 percent? You can’t see it. Better to be safe than sorry?”

Cuyahoga Falls, Ohio-based Ultronic Inc. manufactures disinfectants systems for salons, spas and barbershops. The company’s mission is to offer optimum protection for salon personnel and clients. “Infection control standards in the beauty and barber industry have been upgraded in most states to reflect the new CDC guidelines that were issued in June 2003,” says general manager Gerri Cevetillo-Tuccillo. Two of the organizations that have been diligent in following CDC recommendations are the National Interstate Council of State Cosmetology Boards and the National Association of Barber Boards of America.

“Recent breakthroughs in the testing of disinfectants under a heavy organic soil load and in hard water conditions reinforces the efforts of these governing agencies by offering solutions to regional problems (hard water),” Cevetillo adds. “It also further ensures the effectiveness of the disinfectants used in the salon setting, since all of the implements that are used are exposed to organic and cellular material (hair, nails and skin). Most implements are not pre-cleaned before disinfection, due to time constraints and poor habits. The ability to accomplish both cleaning and disinfection in one step is practical and far more protective.”

And to consider other areas of exposure, Ali Javadian, PhD, states, “When I hear about testing these products in 95-98 percent organic soil load, I think of facilities where there is a lot of blood, whether human or animal in veterinary hospitals. When surfaces are cleaned initially, who is to say what the actual residue soil load is on the surface? EPA standards I believe state that the acceptable test for

efficacy against any pathogen is at a 5 percent organic soil load. So I think, can you tell in some way that you have wiped up 95 percent of them before disinfecting the surface? It sounds rather inadequate to me.”

Rutala adds some validity to the need for disinfection in high soil load when he writes, “Disinfectants are needed for surfaces contaminated by blood and other potentially infective materials (OPIM). In the U.S., in order to comply with the Occupational Safety and Health Administration (OSHA) rule on bloodborne pathogens, a blood spill must be cleaned using a disinfectant. The compliance directive states that the blood should be disinfected using an EPA-registered hospital disinfectant, a disinfectant with a HBV/HIV claim, or a solution of 5.25 percent sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water.<sup>3</sup> A study demonstrated that in the presence of blood spills, a 1:10 final dilution of bleach should be used to inactivate bloodborne viruses.<sup>4</sup> Even at this concentration, complete inactivation cannot be assured.”

Philip Tierno, PhD, director of clinical microbiology and immunology at New York University Medical Center, adds, “There are many reasons why you would want a germicide that would function in a water environment that may not be in the best chemical condition ... with minerals. Another thing, in regards to the soil bio load, many germicides are inactivated by heavy soilage. So one that can sustain its efficacy during intrusion by soil would be an advantageous product just by definition.”

Rodney Stine, with OSHA Review in Sacramento, Calif., services the dental area. He adds, “My position is that nobody should use anything that is not approved by the EPA. What they use should be labeled for that purpose, that function, that specific pathogen. The most important thing about disinfectants is their ability to be effective whenever you have large amounts of organic soil because busy staff members usually use the disinfectant as the cleaning media.”

Medical facilities have a strict regimen of cleanliness. Therefore, the benefits of testing disinfectants for efficacy under “dirty” conditions are often seen as debatable. The point is, medical facilities seldom achieve their own standard of cleanliness. For example, hospitals have high standards for when staff must wash their hands, but study after study has shown that only approximately 35 percent meet that standard.”

Loretta Fauerbach points out, “Infection control professionals teach that disinfectants are to be used according to the manufacturer’s directions at the appropriate use dilution. So if the user followed the directions to remove the organic load prior to disinfection, there should be no problem.” However, this is the precise problem. Busy staff will not always read labels carefully. Often non-English speaking personnel use the disinfectants, though their reading of the printed information on the bottle may be limited. Using a cleanser/disinfectant

rather than relying on staff to clean first and then disinfect is more reflective of real world conditions.

Martin Favero, PhD, director of scientific and clinical affairs at Advanced Sterilization Products in Irvine, Calif., and formerly with the CDC, agrees with Fauerbach, taking it one step farther: “Intermediate and low-level disinfectants are targeted to environmental surfaces and / or they are used for housekeeping purposes.” He adds, “When the new CDC guidelines are published, there will be a section where they talk about whether you need an antimicrobial agent in a detergent when you clean a hospital.”

Sanja Valentic, senior product manager for environmental decontamination and instrument transport at Mentor, Ohio-based STERIS Corporation says, “We’re moving toward new products with new infection control needs, new pathogens, and using new methods to control and to test them. Microgen and STERIS are both in line with changes that are happening globally. We’re looking at prolonged efficacy. We’re looking at new pathogens. We’re looking at new testing techniques. In the marketplace, we’re keeping ahead of where it stands. Our background is in acute care, especially in hospitals where quality infection control is imperative. We’re not a janitorial supply company. We have a science base to all of our testing and all of our practices.”

### **Taking It to the International Level**

Many countries in Asia, Africa, and even Europe have been hit with extremely virulent disease outbreaks, both human and animal. Does the importance of how a disinfectant is tested change when disinfectant products are used in less than hygienic areas of the world?

Cheyne Gable of Marietta, Ga.-based ATCO International believes that testing is important. “The importance of testing a disinfectant under higher soil loads and in hard water conditions becomes even more important under such circumstances,” he claims. “Disinfectant manufacturers have historically tested products in fairly benign laboratory conditions. The problem is that these conditions do not always adequately represent the conditions in which the products may be used, especially in areas of the world that have different hygienic standards. We have seen the effects that a regional outbreak, such as SARS, can have on the rest of the world in such a short period of time. The efficacy of disinfectants is no longer a regional but rather a global matter.

Reid does not believe this is an important issue. He says, “In my view, attention to process and protocols are more important than individual disinfectant efficacies. The global community and movement of people, animals and produce require attention to detail and the identification of control points in these systems. Risk-based prioritization of surveillance and the application of Hazard Analysis and Critical Control Point (HACCP)- based principles will be instrumental in this

control and risk mitigation. Disinfection has a key role to play at certain control points.”

Favero offers another important point, stating, “I believe that cleaning followed by a disinfectant, even one that may be a little compromised would end up being of the same importance in the U.S. or in a developing country.”

Fauerbach adds, “In many third-world countries simple means of cleaning are used such as soap and water and disinfection may be done with chlorine bleach, which is not very expensive.”

Javadian believes that it is up to the companies that manufacture good disinfectants to make sure their products get to the areas most in need, and is an advocate of high OS testing. “I travel a lot in relation to my job and what I see, particularly in places like South Africa and Asia, they are really lacking in even basic hygiene. That is why I encourage all these companies to get their products one way or another to those countries. A 95 percent soil load testing of these quat agents is important. I have seen the long list of efficacy against viruses, fungi and bacteria. On the global level, in all developing countries they need these types of agents (disinfectants) to prevent the spread of disease as much as possible. This goes back to even the hospital settings which are very different from the sophisticated hospitals of the more developed countries.”

Germs hide in soil where they reproduce. Organic soil is a protected shell of food for them. The authorities are unanimous on one thing: Get rid of food waste. Upgrade hygiene standards; clean first, then use a disinfectant, regardless of how effective a disinfectant is in the presence of soil. Most any disinfectant is better than no disinfectant; one rated for use in high soil load may have added benefits.

## **Conclusion**

In the U.S., the EPA has been given the authority by Congress to set the standards for all disinfectant efficacy claims. This body has approved the claims of disinfectants tested for pathogen efficacy under much higher than required OS load and in hard water. The user only has to read any product label to see whether it has been tested for efficacy under enhanced conditions.

The cleaning step is an important one to remove bioburden and make any disinfectant more productive, however, cleaning may not be performed adequately.

Matthew Arduino, of the CDC, concludes, “The labels of EPA-registered disinfectants usually specify that the product is to be used on a pre-cleaned surface. In our opinion, if people followed label instructions consistently, the need to verify that the products worked in the presence of high organic loads would be

reduced. People, however, often do not clean surfaces as they should, so the potency testing in the presence of high organic loads continues.”

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