Choosing Safe & Effective Disinfection in the Post-COVID-19 World

An Exploration of Available Methods

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Abstract

This white paper explains in practical, fact-based terms the important differences in SARS-CoV-2 disinfection products and methods. In addition, it provides useful information to owners and operators to help better inform them about the different choices they have and help to select the right option for their needs.

Commercial and institutional facility owners and operators should carefully select appropriate cleaning and disinfection methods to ensure hard, impervious surfaces within interior spaces are safely and effectively disinfected. Only disinfectants on the U.S. Environmental Protection Agency's (EPA's) List N are authorized for use against SARS-CoV-2. There are important differences in both relative toxicity of different disinfectants and the relative risk in how they are applied to treat hard, impervious surfaces. These differences, in turn, raise critical considerations of safety, efficacy, and practicality. The use of conventional products, when used in accordance with master label use instructions, are generally safe and reliable. Fogging applications which disperse the disinfectant in the air over a wide area pose greater relative risks, which is reflected in their complex and time-consuming use protocols, such as respirators, sealing of room spaces and HVAC systems, and longer wait times for re-occupancy to ensure safety, efficacy, and compliance with federal law—the Federal Insecticide Fungicide & Rodenticide Act (FIFRA). The airborne nature of disinfectants applied by fogging and their greater associated health risks pose special challenges which increase risks and costs and clearly are not a substitute for manual cleaning techniques.

Disclaimer

The reader is apprised of several caveats. First, the information presented is not medical or legal advice. Rather, it is a summary and analysis of specific guidance provided by the U.S. Centers for Disease Control (CDC), the EPA, and other identified sources. Second, the guidance relates only to the regulatory environment in the U.S. and is not applicable outside the U.S. Third, individual states and municipalities may have additional, different or conflicting guidance on disinfection and cleaning methods. The reader is advised to consult state and local guidance for jurisdiction-specific requirements. Fourth, the use and application of disinfectants to kill the SARS-CoV-2 virus is a rapidly evolving area. While the information presented is believed to be current as of the date of this revision the reader should consult with the CDC, EPA, and other sources for up-to-date guidance and information.

Introduction

Our collective shock at the arrival of the COVID-19 pandemic, officially declared a public health emergency on March 13, 2020, has now been replaced with a focused determination to maintain the safety of reopened public spaces through proper cleaning and disinfection. This whitepaper is intended to help guide commercial and institutional facility owners and operators on the selection and use of appropriate cleaning and disinfection methods to safely and effectively disinfect hard, impervious surfaces within interior spaces. We examine the key role played by the pesticide registration process and the labeling of disinfectant products, including a discussion of why

fumigation methods that rely on vaporization or aerosolization of the disinfectant—commonly referred to as "fogging," "misting", and "fumigating"—pose special challenges and potential risks associated with the difficulties and limitations of the application method. Important differences in choices of disinfection products and methods of applying disinfectants and related considerations of safety, efficacy, and practicality should be carefully weighed before choosing disinfectant means and methods.

Important Facts About SARS-CoV-2

We summarize here some relevant facts about SARS-CoV-2 (the virus that causes COVID-19 disease), which helps inform these important decisions.

Over the course of the past year, the SARS-CoV-2 virus has spread broadly from its initial emergence in the city of Wuhan, China, with significant mutations occurring in that timeframe. Since the virus was first identified in December of 2019, three additional variants have been identified as of March 10, 2021[1]:

1. Variant B.1.1.7, first identified in the United Kingdom mid to late 2020 and first identified in the United States in December, 2020. Recent research has indicated that this strain is more transmissible and more deadly than the original strain.[2]

2. Variant B.1.351, originally detected in South Africa in early October and first identified in the United States at the end of January 2021.

3. Variant P.1 was first identified in the United States in January 2021 following initial detection in Japan amongst travelers arriving from Brazil; the variant may have increased resistance to antibodies.

While each of these variants may increase the transmissibility of the virus, there currently is no evidence indicating that the different variants are any more resistant to disinfection with the methods described below.[3]

The SARS-CoV-2 virus is highly contagious and may be transmitted through multiple vectors. The virus is transmitted primarily through respiratory droplets projected when a person coughs, sneezes, or talks in close contact with another person, which the CDC refers to as droplet transmission. Airborne transmission, caused by inhalation of smaller respiratory droplets that

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[1] CDC, *About Variants of the Virus that Causes COVID-19* (Last reviewed March 10, 2021) https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html.

[2] Challen R, Brooks-Pollock E et al. Risk of mortality in patients infected with SARS-CoV-2 variant of concern 202012/1: matched cohort study BMJ 2021; 372 :n579 doi:10.1136/bmj.n579

[3] According to the EPA, "disinfectants work by chemically inactivating viruses. The difficulty of killing a virus depends on its physical features, and the recent mutations to SARS-CoV-2 have not changed the basic physical properties." EPA, "Do disinfectants kill newer strains of coronavirus?", *Frequent Questions about Disinfectants and Coronavirus (COVID-19)* (last reviewed March 11, 2021) https://www.epa.gov/coronavirus/do-disinfectants-kill-newer-strains-coronavirus

linger in the air for longer and travel a greater distance through the air, also is a significant means of transmission. This is particularly an issue in enclosed spaces with inadequate air ventilation, filtration or handling, and/or where an infected person is engaging in expiratory exertion (*e.g.*, shouting, singing, and exercising).[4] Another vector, known as the fomite transmission method, involves a person becoming infected after making contact with contaminated surfaces like countertops, tabletops, door handles, and other high-touch hard surfaces and then touching their mouth, nose, eyes, and/or face.[5] Asymptomatic people—those with no disease symptoms—can carry the virus and contaminate surfaces unknowingly. SARS-CoV-2 can survive on impervious surfaces for at least a few hours to a few days, with warmer temperatures and exposure to sunlight reducing the time the virus survives on surfaces and objects.[6] However, like most so-called "enveloped viruses" SARS-CoV-2 easily can be deactivated or killed with standard disinfection techniques.[7] Cleaning of visibly dirty surfaces followed by the application of a disinfectant in accordance with instructions is effective at killing the virus and therefore is considered a best practice measure for prevention of COVID-19 (and other viral respiratory illnesses) in commercial and institutional facilities, households, and community settings.

Thus, the CDC recommends reducing the risk of exposure to COVID-19 by regularized "cleaning" (the removal of visible dirt, germs, and impurities from surfaces), followed by "disinfection" (the killing of remaining germs on surfaces) using a disinfectant registered with the EPA that has been tested and proven to be effective.[8] The CDC does not recommend the use of alternative disinfection methods, such as ultrasonic waves, high intensity UV radiation, and LED blue light because their efficacy against the SARS-CoV-2 virus is not known.[9] The same is true of sanitizing tunnels, which the CDC specifically recommends not using, citing "no evidence that they are effective in reducing the spread of COVID-19."[10]

In view of this knowledge about SARS-CoV-2, institutional, commercial, and industrial facility owners and operators are on notice of the role of contaminated impervious surfaces in the transmission of the COVID-19 disease. While studies continue to emphasize that airborne and droplet transmission are primary vectors of transmission of SARS-CoV-2, preventing transmission

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[4] CDC, *Scientific Brief: SARS-CoV-2 and Potential Airborne Transmission* (last updated Oct. 5, 2020). Person to person contact and droplet transmission is much more common.

[5] *Id*.; CDC, *How COVID-19 Spreads* (last reviewed April 13, 2020); CDC, *Cleaning and Disinfection for Households Interim Recommendations for U.S. Households with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19)* (May 7, 2020); CDC, *Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes* (last updated May 7, 2020).

[6] Department of Homeland Security, Science and Technology Master Question List for COVID-19 Weekly Report (March 25, 2020).

[7] CDC, *Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes* (April 28, 2020).

[8] CDC, *Cleaning and Disinfection for Households* (last updated July 10, 2020); CDC, *Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes* (last updated May 7, 2020); CDC, *Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes* (April 28, 2020).

[9]CDC, Cleaning and Disinfecting Your Facility Everyday Steps, Steps When Someone is Sick, and Considerations for Employers (last updated July 28, 2020); CDC, *Coronavirus Disease 2019, Cleaning and Disinfecting Your Facility Everyday Steps, Steps When Someone is Sick, and Considerations for Employers* (last reviewed April 4, 2020).

[10] *Id*.

through high-touch surfaces also remains a priority. Clients and customers expect and demand safe, reliable, and effective disinfection solutions to help prevent this disease transmission in compliance with CDC and EPA guidelines.

Important Considerations When Selecting a COVID-19 Disinfectant

Careful selection of disinfectants and methods of use is essential to avoid unintended harm that might result from choosing an improper disinfectant or misusing one that is otherwise proper. An end-user will want to be confident about the adequacy of the disinfection and the safety of the process. Failure to implement and follow proper disinfection protocols increases risk of infections and exposes facility owners and operators to legal liability in tort. Also, personnel using disinfectants must strictly follow EPA disinfectant label instructions, including specifically how the disinfectant can be applied (e.g. via a conventional pump sprayer but not an electrostatic sprayer), which are designed to ensure both the safety of the user, other people, and the environment, and the effectiveness or "efficacy" of the disinfectant to achieve the desired elimination of the pathogen. Failure to strictly follow disinfectant use instructions on product labels regulated by the EPA may expose those persons applying the disinfectant to possible violations of federal law carrying both civil and criminal penalties.

The Overlapping Roles of Government Agencies

Several federal agencies have responsibility for guiding SARS-CoV-2 disinfection, namely the CDC (a component of the U.S. Department of Health and Human Service (DHHS)), the EPA, the U.S. Food and Drug Administration (FDA), and the Occupational Safety & Health Administration (OSHA). State and local health departments also have an important role, as do research institutions and the National Institutes of Health (including the National Institute of Allergies and Infectious Disease).

CDC

The CDC's primary role is the protection of human health and safety from disease through scientific research and the dissemination of public health information. The CDC provides advice on infectious disease prevention, including on the use of disinfectants to kill pathogens such as SARS-CoV-2, based upon its expertise in public health and medicine. The CDC conducts epidemiologic investigations and disseminates guidance and other information to the public in the event of a disease outbreak. The CDC is constantly updating its guidance and as of this writing maintains 177 guidance documents relating to COVID-19, including testing, contact tracing, worker safety, travel safety, and cleaning and disinfection in various settings. The CDC does not have regulatory or enforcement authority over means and methods for disinfection or over the devices and/or medicines used for prevention and treatment.

EPA

The EPA is the primary regulatory and enforcement authority for the use of disinfectants to kill pathogens that threaten public health, such as SARS-CoV-2.[11] The EPA acts pursuant to its authority to test and label disinfectants to ensure safety and efficacy under the FIFRA. FIFRA forbids any person to use any registered "pesticide" in a manner inconsistent with its labeling. A "pesticide" is any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any "pest," which includes viruses, bacteria, or other micro-organisms. EPA strictly regulates disinfectants (also known as "antimicrobials" or "antimicrobial pesticides") used to kill or deactivate micro-organisms which threaten public health, such as the SARS-CoV-2 virus. The standard of care for disinfection generally requires the use of only those disinfectants EPA has authorized for use on the SARS-CoV-2 virus and in a manner consistent with their label instructions. Care must be exercised to ensure that the registered disinfectant is used in a manner consistent with its label instructions, as a failure to do so is a violation of FIFRA.

The EPA has responsibility to ensure that disinfectants proposed for use to kill pathogens like SARS-CoV-2 are safe and effective prior to registration. EPA has published a list of authorized SARS-CoV-2 disinfectants, known as "List N" (https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19). As of March 10, 2021, the list contains five-hundred and thirty-seven (537) products. EPA frequently updates List N, which identifies those surface disinfectant products that will kill the SARS-CoV-2 virus based upon demonstrated efficacy against harder-to-kill viruses or other types of human coronavirus similar to SARS-CoV-2. One hundred and sixteen (116) of those registered products have shown specific efficacy against SARS-CoV-2. A disinfectant used to kill SARS-CoV-2 must achieve strict performance levels under the specific usage instructions.[12] Most of the surface disinfectants on List N are registered for and can be used to kill viruses on hard impervious (or nonporous) surfaces such as counters, desks, doorknobs, and equipment, provided the label instructions are strictly followed. Porous surfaces pose unique challenges further discussed below.

EPA also provides general guidance on reducing the spread of SARS-CoV-2, including on the use of disinfectant products on surfaces, air sanitization, and impact on water supplies. This guidance,

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[11] The FDA retains authority over medical devices and drugs. Medical devices and drugs used for the treatment or prevention of COVID-19 are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA). While this would include vaccines and treatments subject to much public discussion, it would also include prevention methods. For example, gowns, other apparel, and gloves are regulated by FDA as a "device" under the FDCA when used for a medical purpose. In addition, hand sanitizers are regulated as an over-the-counter drug available without a prescription. Like the EPA, the FDA also keeps a list available to the public as it relates to hand sanitizers (https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use#products). However, the FDA's list is a "Do Not Use List" or recall list for certain products. Like the EPA, the FDA also has a registration process for hand sanitizer products and has issued several guidance documents to make transition to the manufacture and sale of alcohol-based hand sanitizers easier during the current public health emergency. *See, e.g.*, FDA, *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry* (March 2020).

[12] EPA, *Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for USE on Environmental Surfaces Guidance for Efficacy Testing* (Feb. 2018).

in addition to jointly-developed guidance with the CDC, is presented through a regularly updated Frequently Asked Questions section on EPA's website (https://www.epa.gov/coronavirus).

The CDC and EPA guidance documents often are complementary. For example, as it relates to general guidance for usage of List N products, the EPA has published an infographic titled "6 Steps for Safe & Effective Disinfectant Use,"[13] a tool the CDC frequently refers to in its own guidance documents. The steps include: (1) check that your product is EPA-approved; (2) read the directions; (3) pre-clean the surface if directed by the label; (4) follow the contact time; (5) wear gloves and wash your hands; and (6) lock it up. CDC's infographic, while not a substitute for the specific label instructions, helps users understand the basics of proper disinfection protocols. Similarly, with the reopening of schools, the EPA has announced increased focus on childhood safety.[14] EPA's brochure for this initiative, like the CDC's infographic, provides a list of simple steps to ensure the proper use of registered products (e.g. avoid fogging unless specifically registered for that application), or if registered products are unavailable, use of an alternative disinfectant (e.g. properly diluted bleach), consistent with CDC guidance.[15]

OSHA

OSHA is the primary regulatory and enforcement authority over workplace safety under the Occupational Safety and Health (OSH) Act of 1970. Its authority includes measures for protecting workers from exposure to infection from SARS-CoV-2. The "general duty clause" under Section 5(a)(1) of the OSH Act mandates that employers furnish employees with a place of employment free from recognized hazards that could cause death or serious physical harm. To that end, OSHA has Personal Protective Equipment (PPE) standards, along with a specific Respiratory Protection standard, that may be applicable when entering an area known to be contaminated with SARS-CoV-2 and/or when using certain chemicals for cleaning and disinfection. The usage of certain chemicals used to kill SARS-CoV-2 may trigger not only PPE standards, but also other OSHA standards relating to hazardous chemicals.[16] Like the EPA, OSHA retains enforcement authority over the statutory and regulatory requirements of the OSH Act. It has issued a series of enforcement documents to assist employers dealing with this challenging time.[17] It has also issued a series of guidance documents specifically tailored to employers in various settings.[18] As it relates to cleaning and disinfection, OSHA has issued a National Emphasis Program(for COVID[19], and generally refer employers to the CDC standards, which, of course, incorporate EPA's efforts.[20]

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[13] EPA, 6 Steps for Safe & Effective Disinfectant Use, *available at* https://www.epa.gov/pesticide-registration/six-steps-safe-effective-disinfectant-use.
[14] EPA Press Release, *Protecting Children During the COVID-19 Public Health Emergency* (Oct. 19, 2020).
[15] EPA, *Protecting Children's Health* at pp. 5–6 (Oct. 2020).
[16] OSHA, *COVID-19: Standards* webpage, *available at* https://www.osha.gov/SLTC/covid-19/standards.html.
[17] *Id.*
[18] OSHA, COVID-19: Additional Resources webpage, *available at* https://www.osha.gov/SLTC/covid-19/additional_resources.html.
[19] OSHA, *National Emphasis Program – Coronavirus Disease 2019 (COVID-19)*, DIR 2021-01(CPL-03), (Mar. 12, 2021), *available at https://www.osha.gov/enforcement/directives/nep*
[20] *See* OSHA, *COVID-19: COVID-19 Frequently Asked Questions* webpage, *available at* https://www.osha.gov/SLTC/covid-19/covid-19-faq.html#collapse4 (referring employers who ask "How should I

OSHA and the CDC have cooperated for many years given their shared mission; for example, the CDC's National Institute for Occupational Safety and Health (NIOSH) provides research and guidance for safety in the workplace setting.

State and local public health and environmental agencies also have a major, front-line role in controlling infectious diseases through their traditional police power exercised by the various state and local departments of public health. They generally have the authority to investigate and mitigate contagious and infectious disease outbreaks and to define and abate nuisances dangerous to the public health, including directing building owners to clean and disinfect. States also have been delegated authority to enforce use of disinfectants and other pesticides under FIFRA, typically through state departments of agriculture. Four states – Virginia, Michigan California and Oregon – have implemented their own standards for cleaning and use of PPE. There are also twenty-eight (28) OSHA-approved state plans that, in some instances, may impose even more stringent PPE or chemical handling standards than OSHA requirements.

Choice of Disinfectant Active Ingredients & Application Methods Has Important Implications for Safety & Efficacy

Classes of Active Ingredients

There are multiple active ingredients used in disinfectants listed on EPA's List N, each of which presents unique benefits and challenges from an efficacy and safety perspective. EPA has expedited all requests for inclusion of products on List N in order to assure that users have sufficient access to products shown to be effective against the coronavirus. EPA has been concerned about assuring an adequate supply of products that can meet a particular user's needs and circumstances. While we mention certain products here, it is important to pay careful attention to the labeling for any and all products on List N.

Of the five hundred and thirty seven (537) products included on List N as of March 10, 2021:

- Two Hundred and forty seven (247) products include quaternary ammonium compounds, or "quats," as a primary active ingredient. Quats are some of the most common compounds for antimicrobial applications, such as Lysol Brand All Purpose Cleaner spray (EPA Reg. No. 777-66) and Clorox Disinfecting wipes (EPA Reg. No. 67619-31). Quats are also utilized in fabric softeners, hair conditioners, and plant growth retardants.
- Two-hundred and eight (207) products include various bleach and bleach-like compounds (e.g. hydrogen peroxide), including chlorine compounds, such as sodium chlorite (e.g. Parox Hospital Disinfectant, EPA Reg. No. 6951, sodium hypochlorite (e.g. Soft Scrub with Bleach, EPA Reg. No. 64240-44), chlorine dioxide (e.g. Oxine, EPA Reg. No. 9804-1), hydrogen peroxide (e.g. Clorox Commercial Hydrogen

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clean and disinfect my workplace?" to the CDC website); OSHA, *COVID-19: Control and Prevention* webpage, *available at* https://www.osha.gov/SLTC/covid-19/controlprevention.html#environmental_cleaning ("OSHA and the U.S. Department of Health and Human Services (HHS) provide joint guidance for all employers on preparing workplaces for COVID-19") (referring employers to the CDC instructions for environmental cleaning and disinfection for various types of workplaces).

Peroxide Cleaner, EPA Reg. No. 67619-24), and hypochlorous acid (e.g. Cleansmart, EPA Reg. No. 89896-2). Bleach is frequently used as a disinfectant, in addition to use as a stain remover.

- Thirty Nine (39) products contain or utilize either isopropyl alcohol (e.g. Klercide 70/30 IPA, EPA Reg. No. 1677-249) or ethanol (e.g. Purell Surface Disinfecting Wipes, EPA Reg. No. 84150-1). Alcohol products have broad acceptances as active ingredients in antimicrobial products.
- Twenty Nine (29) products include phenol derived compounds.
- Thirty Two (32) products contain naturally-derived disinfectant products considered to pose less risk, including lactic acid (e.g. Windex Disinfectant Cleaner, EPA Reg. No. 4822-593), glycolic acid (e.g. Pine-Sol Multi-Surface Cleaner, EPA Reg. No. 5813-101), thymol (e.g. Benefect Broad Spectrum Disinfectant, EPA Reg. No. 84683-1), or citric acid (e.g. Comet Disinfecting Bathroom Cleaner, EPA Reg. No. 3573-54). While these products generally require a greater period of contact to be effective, they may present fewer risks.[21]

EPA-Approved Application Sites on List N

As part of the EPA's approval process for marketing a given product, disinfecting claims are limited to a specific type of application site. For example, EPA maintains separate testing protocols for using products on hard non-porous surfaces, food contact surfaces, fabrics and textiles, air, or in water. Of the five-hundred and thirty seven (537) products on EPA's List N as of March 10, 2021, three-hundred and twenty nine (329) are approved only for use on non-food contact hard, nonporous surfaces, with an additional one-hundred and ninety nine (199) products approved for both food contact and non-food contact applications. Only nine (9) of the approved products are approved for use with porous surfaces, specifically as a laundry additive. No products on List N are currently approved for air disinfection,[22]although EPA has issued "Emergency Exemptions" pursuant to Section 18 of FIFRA (also called "Section 18s") authorizing unregistered uses of a triethylene glycol disinfectant for air treatment in enclosed spaces as a supplement to other disinfectant methods.[23]

Toxicity of Active Ingredients

All disinfectants have risk, since they are designed and intended to kill living organisms. But risk is a relative term and some disinfectants certainly may pose greater, long-term risks to custodial workers and building occupants than others. For example, some List N active ingredients are respiratory irritants and sensitizers found to cause or contribute to asthma (*e.g.*, chlorine

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[21] *See generally* EPA, *List N: Disinfectants for Use Against SARS-CoV-2*.
[22] *Id.*
[23] EPA, *EPA Decision Documents for Emergency Exemption Requests for Use Of Grignard Pure* (Jan. 14, 2021) https://www.epa.gov/pesticide-registration/epa-decision-documents-emergency-exemption-requests-use-grignard-pure

bleach/sodium hypochlorite, peroxyacetic acid, and quaternary ammonium compounds) and skin sensitization (*e.g.*, chlorine bleach and thymol).[24]

EPA has established four "Toxicity Categories" for acute hazards of pesticide products, which includes disinfectants.[25] Category I is the highest toxicity category and Category IV the lowest based upon data collected for five types of acute exposures, Oral LD50, Dermal LD50, Inhalation LC50, Eye Irritation, and Skin Irritation. Between 2009 and 2017, EPA's *Design for the Environment Pesticide Pilot Project* (DfE) identified a list of disinfectant active ingredients determined to be on the "green" end of the pesticide spectrum.[26] Disinfectants making the cut qualified for a special product logo on their pesticide labels indicating they: (1) are in the least-hazardous classes (*i.e.*, Categories III and IV) of EPA's acute toxicity category hierarchy; (2) are unlikely to have carcinogenic or endocrine disruptor properties; (3) are unlikely to cause developmental, reproductive, mutagenic, or neurotoxicity issues; (4) contain mixtures that have been reviewed and accepted by EPA, including inert ingredients; (5) have no unresolved or unreasonable adverse effects reported; and (6) have no unresolved compliance or enforcement actions associated with it.[27]

Comparing the disinfectant active ingredients previously qualifying for EPA's DfE pilot program and those on EPA's SARS-CoV-2 List N yields a fairly small group: citric acid, hydrogen peroxide, L-lactic acid, ethanol, isopropanol, and peroxyacetic acid.

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[24] *See generally*, San Francisco Department of the Environment, Green Purchasing Institute (2014), *Safer Products and Practices for Disinfecting and Sanitizing Surfaces;* Holm, S et al., *Do we know how best to disinfect child care sites in the United States? A review of available disinfectant efficacy data and health risks of the major disinfectant classes.* Am J Infect Control 2019;47:82-91; Pechter, E. *Occupational health risks associated with use of environmental surface disinfectants in health care*. Am J Infect Control 2016:1755-63; Quinn MM, Henneberger PK, National Institute for Occupational Safety and Health (NIOSH), National Occupational Research Agenda (NORA) Cleaning and Disinfecting Healthcare Working Group, Braun B, Delclos GL, et al. *Cleaning and disinfecting environmental surfaces in health care: toward an integrated framework for infection and occupational illness prevention.* Am J Infect Control 2015;43:424-34; Arif AA, Delclos GL. *Association between cleaning-related chemicals and work-related asthma and asthma symptoms among health care professionals.* Occup Environ Med 2012;69:35-40.; Rosenman KD. *Cleaning products-related asthma*. Clin Pulm Med 2006; 13:221-8; Delclos GL, Gimeno D, Arif AA, Benavides FG, Zock JP. *Occupational exposures and asthma in health-care workers: comparison of self-reports with a workplace specific job exposure matrix.* Am J Epidemiol 2009;169:581-7; Saito R, Virji MA, Henneberger PK, Humann MJ, LeBouf RF, Stanton ML, et al. *Characterization of cleaning and disinfecting tasks and product use among hospital occupations.* Am J Ind Med 2015;58:101-11; New Jersey Department of Health (2013), *Health Alert Bulletin, Fogging Ambulances with Toxic Disinfectants May Cause Illness.*

[25] 40 C.F.R. 156.62.

[26] *See*, EPA, *Design for the Environment Antimicrobial Pesticide Pilot Project: Moving Toward the Green End of the Pesticide Spectrum, available at* https://19january2017snapshot.epa.gov/pesticide-labels/design-environment-antimicrobial-pesticide-pilot-project-moving-toward-green-end_.html.

[27] *Id.*

Application Methods

The method by which a disinfectant is applied in accordance with its EPA-approved master label[28] also is a significant factor in the relative safety and efficacy of the disinfectant. While all disinfectants registered with and approved by EPA for use on SARS-CoV-2 and other viruses are deemed to pose no unreasonable adverse effects when used in accordance with the label instructions, some products have greater potential risk than others.

In accordance with EPA approved labels, disinfectants may be applied through: (i) manual application methods, such as wipes, towelettes, and cloths, (ii) sprays, or (iii) fumigation methods that rely on vaporization or aerosolization of the disinfectant. The relative risks posed by the three application methods are discussed below. Much information and misinformation is circulating about the use of fogging, fumigation, or similar methods for disinfecting and sanitizing buildings to prevent transmission of SARS-CoV-2. It is worth reminding that **no List N product is approved for disinfection in air,** thus, like the traditional methods, fogging as an application method is still intended to target virus solely on hard surfaces. The choice between this method and others requires consideration of several factors discussed below.

Disinfectant products for use on hard, impervious surfaces contaminated with the SARS-CoV-2 virus come in different forms, including water soluble powders and liquids, spray products, towelettes, and fogging/gas/vapor.[29] The efficacy of a disinfectant depends upon a number of factors that must be controlled, with the most important being contact time (also known as "dwell time" or "kill time"). Contact time requires the surface of materials being cleaned to be wet with disinfectant for the EPA registered identified time. EPA's efficacy testing guideline requires all disinfectants to meet the performance standard associated with the method and microbe at ≤10 minutes of contact.[30] EPA evaluates the success of the viral disinfectants—known as "virucides"—by measuring the residual virus remaining after treatment under the use conditions.[31]

EPA has recently announced plans to expedite the approval process for long-lasting products which can claim effectiveness beyond twenty-four (24) hours.[32] For now, however, consumers in various residential, commercial, or industrial settings are limited to the current products on List N.

Wipes Generally Considered Easy, Safe & Effective

Almost all of the products on EPA's List N are approved to be applied as either a ready to use or dilutable product. Among the approved products as of March 10, 2021, two-hundred and thirteen (213) are ready to use off the shelf liquid products; two-hundred and forty three (243) are dilutable liquids, which are mixed with water prior to application; two (2) are pressurized liquid sprays; four

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[28] Please note that the master label contains far more information regarding potential use sites and approved claims than the market packaging. To review EPA approved master labels, please see the EPA Pesticide Product Label System, available at https://www.epa.gov/pesticide-labels/pesticide-product-label-system-ppls-more-information

[29] EPA, *Product Performance Test Guidelines OCSPP* 810.2200: *Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing* (Feb. 2018).

[30] *Id.*

[31] *Id.*

[32] EPA Press Release, *EPA Administrator Andrew Wheeler Announces Expedited Pathway for Companies to Claim "Long-Lasting" Efficacy for Antiviral Products* (Oct. 14, 2020).

(4) are solids dissolved in water prior to application; and sixty-seven (67) are pre-soaked wipes. With these methods the disinfectant applicator visually confirms the surface has been adequately pre-cleaned to remove organic contaminants, directs and controls where to apply the disinfectant, and confirms both the amount of disinfectant applied and the contact time. There is no need to seal the space to prevent unintended exposures to airborne disinfectant because the disinfectant is in liquid form (applied through wipes or spray) during its application.

Pre-soaked wipes and liquids applied by cloth provide the most control for the applicator and offer the fewest opportunities for excessive application or unintended exposure. Because these methods do not require any aerosolization or spraying mechanism, there is a reduced risk for inhalation by the applicator. Additionally, the use of a wipe or cloth applicator helps ensure that surface organic matter can be effectively removed.

Sprays (Conventional and Electrostatic) Pose Several Challenges

Sprays provide an alternative means for applying disinfectant products to hard surfaces. The individual applicator targets the spray directly onto the surface, allowing the applicator to observe potential surface organic matter. However, spraying does present some additional risk for health impacts during application, as it may aerosolize the product, which can be inhaled, and it utilizes a larger amount of antimicrobial product than a wipe or cloth, which may pose greater risk of exposure. It also is less precise in its application than the use of mechanical means and does not remove surface organic matter, unlike wipes, which have the added benefit of friction to remove organic matter in the process of application.

Electrostatic spraying is a form of spray application that warrants additional caveats. With an electrostatic sprayer, droplets of liquid disinfectant are positively charged to make the droplets electrically stronger than the surface being treated. Similar to magnets, the charged droplets are drawn to each other and attach when one surface is more positively charged than the other. Under ideal conditions (ambient temperature and humidity) an electrostatically-charged spray solution surrounds the object and is believed to result in more uniform distribution of the disinfectant, particularly over uneven surfaces compared to conventional spray systems.[33] However, electrostatic spraying requires pre-cleaning of the surfaces and typically the use of professional applicators to ensure effective antimicrobial activity. It also generally is more time consuming to effectively implement, requires the use of an N95 mask, and requires ideal ambient conditions of temperature and humidity. Finally, the use of electrostatic spray application must be specifically authorized by the disinfectant product label. Merely because the label of a List N disinfectant product authorizes it to be applied via spraying *does not mean that electrostatic spraying is authorized*. Before a disinfectant can be approved for electrostatic spraying, it must undergo efficacy testing and EPA approval to verify it is effective when used with an electrostatic spray device.[34] The product label will then explicitly state that the disinfectant may be used with an

[33] EPA, *Application of Electrostatic and Backpack Sprayer Systems for Decontamination of Building Materials Contaminated with Malathion* (Nov. 2015).
[34] EPA, *Expedited Review for Adding Electrostatic Spray Application Directions for Use to Antimicrobial Product Registrations* (Oct. 2020).

electrostatic spray device. If the product label does not explicitly state that it may be used with an electrostatic sprayer, the use of an electrostatic sprayer is prohibited by FIFRA because such use is not in accordance with product label.[35]

Fumigation Methods, including Foggers and Misters, Pose Even Greater Application Complexity and Challenges

Fumigation methods disperse the disinfectant through the air within a secured space. The air becomes saturated with the disinfectant which then falls onto surfaces within the secured area. Such methods function by saturating the air with a prescribed concentration of vaporized or aerosolized disinfectant over a defined period of time.[36] Airborne methods for applying a disinfectant are inherently less controlled and commonly may be referred to as "fogging," "misting", and "fumigating."[37] Disinfectants applied through these airborne methods are not tested in the same way as manual methods (*e.g.*, liquids, spray products, towelettes) but are subject to case-by-case testing methodologies that must be developed in consultation with EPA.[38]

As discussed above, only disinfectants on EPA's List N should be used to disinfect spaces to help prevent transmission of SARS-CoV-2. EPA's List N contains a limited number of disinfectants that can be applied through fogging/misting for use against SARS-CoV-2. Precisely which products may be used in a fog/mist application requires a detailed review of each product label to determine which ones have use instructions that align fogging/misting with the viral disinfection claims. Currently, only three (3) List N products are approved for ready-to-use fogging application, while two (2) additional products are registered for ready-to-use vapor application with approved equipment. All five (5) List N products approved for fogging and/or vaporizing use HP as the active ingredient.

Only five (5) disinfection products on List N can be applied by fogging or vaporizing because standardized testing protocols to demonstrate efficacy using these wide-area application methods are not available. EPA's registration process for antimicrobial products requires the applicant to submit data showing that it is able to effectively kill a given pathogen when applied in accordance with its label. For the majority of application types, such as hard non-porous surfaces or laundry disinfection, EPA's guidance and regulations outline the specific testing methodologies an applicant must use to show efficacy, for example, by utilizing consensus testing protocols developed by either ASTM International or AOAC international.[39] However, no such standardized

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[35] *Id.*

[36] EPA, *Summary of the Effectiveness of Volumetric Decontamination Methods as a Function of Operational Conditions*.

[37] *See* EPA, *Can I apply a product using a method that is not specified in the directions for use on Coronavirus (COVID-19)?* (April 17, 2020); EPA, *Can I use fumigation or wide-area spraying to help control COVID-19?* (April 17, 2020).

[38] EPA, *Product Performance Test Guidelines OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing* (Feb. 2018).

[39] *See generally* EPA, *Series 810 – Product Performance Test Guidelines* (last updated February 2018).

testing protocol for efficacy demonstration exists for fogging, vaporizing or misting applications, which must be developed case-by-case.

EPA has not adopted formal guidance on the appropriate testing methodology for fogger or misters. Applicants are required to submit a draft testing protocol for approval by EPA prior to conducting efficacy testing.[40] As a result, applicants seeking approval of fogger or mister products face a much higher burden of developing or adopting a testing protocol, compared to more conventional products which are tested pursuant to well-established consensus standards. In the absence of a shift in EPA policy, it is therefore unlikely a significant number of new fogging products will be approved for List N.

Usage of the five (5) approved List N products applied by fogging/vaporizing is made more difficult by several challenges. Some of these products exist in dilutable (i.e. concentrated) form, which requires the applicator to follow proper dilution ratios in accordance with EPA-approved use directions. Others require use of specific application equipment. For example, one product on EPA's List N, TOMI Environmental Solutions, Inc., Binary Ionization Technology (BIT) Solution (EPA Reg. No. 90150-2), for healthcare, institutional, and residential use (7.8% HP aerosol), requires use of special equipment which generates HP aerosol. Certain other fogger, mister or vapor products on List N have labels authorizing application only under very specific, limited conditions that do not apply to most residential, educational, retail, or mass gathering applications. For example, the Vaprox Hydrogen Peroxide Sterilant (EPA Reg. No. 58779-4), is expressly not for residential use; instead, its use is limited to "industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing including clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles)." ." Accordingly, it is important to carefully review List N product labels before making a determination that a disinfectant on the list can be used in a fogging application for specific property use (*e.g.*, general institutional or commercial use).

Health Challenges Associated with Disinfectant Fogging Application

For those virucidal disinfectants labeled to permit application by fogging, expect to find complex instructions that pose challenges for safely managing the active ingredients which are airborne. Airborne disinfectants pose safety concerns because these products carry greater potential risks to people and the environment compared to disinfectant wipes or sprays.

Elevated risks associated with inadvertent exposures to disinfectants applied through wide-area application methods are well-documented.[41] For example, the New Jersey Department of Health strongly recommends against fogging of ambulances with quaternary ammonium after finding that

[40] EPA, *Fogger and Mister Final Signed Letter to Registrants* at 3–4 (April 1, 2013).
[41] See New Jersey Department of Health (2013), *Health Alert Bulletin, Fogging Ambulances with Toxic Disinfectants May Cause Illness*; see also, CDC (2018), *Illnesses and Injuries Related to Total Release Foggers --- Eight States, 2001 – 2006*, Weekly Morbidity and Mortality Weekly Report.

emergency responders were sickened by residual exposure.[42] "Fogging uses a fine mist to kill microorganisms and generates micro-particles (and possibly nano-particles) of disinfectant . . . which can be absorbed into the body much quicker and in greater quantities than larger particles . . . the long-term consequences of converting disinfectant from liquid to dry mist (i.e. fogging) are unknown."[43] Similarly, the Connecticut Department of Public Health recommends against the use of fogger/misters in school settings:

> the spraying or fogging of disinfectants in large quantities in school settings may lead to increased adverse respiratory and dermal issues for students and staff and does not replace the need for regular manual cleaning techniques, in turn potentially adding significant and unnecessary cost to school budgets.[44]

Notably, the few EPA-approved, ready-to-use fogging and vapor products on List N to date are not quat based.

Due to these risks, instructions for use of fogging disinfectants may also require detailed planning and protocols, perhaps even a formal Fumigation Management Plan (FMP) specific to State guidelines, to ensure the safety of the applicator and other people, including bystanders located outside the containment zone.[45] Generally, under the terms of labeling of these types of products, prior to treatment, the treatment area must be fully evacuated and sealed,[46] including HVAC systems, to prevent leakage of the disinfectant outside the containment area. Monitoring must also be conducted to ensure building occupants, workers, bystanders, and/or residents are not exposed. For example, HP has an OSHA Permissible Exposure Limit (PEL) of 1.0 ppm (1.4 mg/m) for workers. Dräger tubes to measure ambient levels may be recommended to assure airborne concentrations outside the treatment area remain below the applicable PEL.[47] Depending on conditions and volume, treated spaces may require 5–6 hours following treatment to return to a safe level where others may enter.[48] However, certain absorbent materials, like paper or cardboard, may absorb disinfectant and pose a longer-term risk of off-gassing. If the indicated PEL level is exceeded, instructions may require the treatment process to be immediately aborted to ensure safety. Use instructions may also recommend having a notification plan to alert local emergency authorities if there is an exposure incident.

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[42] New Jersey Department of Health (2013), *Health Alert Bulletin, Fogging Ambulances with Toxic Disinfectants May Cause Illness*;
[43] New Jersey Department of Health (2013), *Health Alert Bulletin, Fogging Ambulances with Toxic Disinfectants May Cause Illness.*
[44] Connecticut Department of Public Health,, *Reopening Schools and Disinfectant Fogging*, EHS Circular Letter #2020-48 (June 15, 2020)
[45] See, e.g., TOMI™ Environmental Solutions, Inc., Environmental Binary Ionization Technology® (BIT") Solution is for use exclusively with the SteraMist™ Environment System.
[46] *Id*.
[47] *Id*.
[48] Freyssenet, C, Karlen, S. (2019), *Plasma-Activated Aerosolized Hydrogen Peroxide (aHP) in Surface Inactivation Procedures*, Journal of ABSA International.

The risks posed by fogging/misting must be carefully managed and may require the use of trained workers. For example, one List N product, the TOMI Environmental Solution 7.8% HP aerosol product, is applied through special aerosolization equipment which generates aerosols that micro-condense and passively fall onto surfaces where they kill SARS-CoV-2 and other microorganisms. HP is generally considered one of the "safer" disinfectants, because it quickly breaks down and leaves behind no residual chemical on treated surfaces.[49] However, even HP poses elevated risks when applied as a fogger since it is a corrosive gas that can cause irreversible eye damage, skin burns and may be fatal if inhaled.[50] HP in vapor or aerosol form poses an inhalation risk to sensitive people, including children and asthmatics. Workers applying HP in vapor or aerosol form must be trained and properly fitted with a respirator, pursuant to an OSHA respirator program meeting the requirements of 29 C.F.R. 1910.134, and wear PPE, such as safety goggles and protective clothing. Another ready-to-use 7% HP fogging product from CURIS System LLC, CURoxide™ (93324-1) for healthcare, institutional, and residential use also requires the use of specific equipment (CURIS® System fogging (misting) equipment) in accordance with that system's user manual. It also requires use of a hydrogen peroxide sensor to monitor the minimum effective concentration, as well as re-entry levels. Finally, the label recommends use of protective eyewear, gloves, long sleeves, and long pants, and at least half-face piece respirator (and appropriate eye protection).

These are merely examples of the fairly extensive precautions required for the application of disinfectants on the low-end of the risk spectrum (i.e. HP) using fogging methods. Of course, the extent of the PPE and other requirements required for safe application of disinfectants varies depending on the hazardous nature of the active ingredient and the process used to apply it. In contrast, wipe methods generally are less hazardous to the operator and possible bystanders compared to fogging/misting/fumigation methods and this is reflected in lesser requirements for PPE and other safety protocols.

Before considering the use of products registered for fogging application, careful consideration should be given to the institution's ability to manage the specific terms of use required for fogging products or the need to spend extra resources to outsource these services to companies using trained personnel.

Efficacy Challenges Associated with Fogging Applications

Fogging systems come with detailed and complex use directions indicated above in order to ensure efficacy. These systems work by spraying a vapor or aerosol mist into the air which falls onto exposed, open surfaces and objects. Disinfectant may not reach unexposed voids, cracks, crevices, drawers, closets, cabinets, undersides, or surfaces covered with papers or other objects where the virus may be present. If the necessary deep cleaning methods to remove dirt and organic matter followed by wiping with a disinfectant are properly conducted, the use of additional wide-area vaporized or aerosolized methods is likely redundant and therefore unnecessary.[51]

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[49] *See* San Francisco Department of the Environment, Green Purchasing Institute (2014), Safer Products and Practices for Disinfecting and Sanitizing Surfaces.

[50] Agency for Toxic Substances and Disease Registry (2015), *Medical Management Guidelines for Hydrogen Peroxide (H202).*

[51] EPA, *Letter to Registrants of Antimicrobial Fogging/Misting Products* (April 1, 2013).

Fogging systems to apply disinfectant are subject to the same contact time per the Master label as conventional application methods such as wipes. For example, HP systems require adequate ambient air concentrations and exposure time to be effective. They generally have contact time of fifteen (15) minutes or less, which is longer than more traditional disinfectants and may be difficult to achieve. As is the case with hand-wiping methods, HP fogger/vapor systems must be preceded by extensive preparation efforts involving manual cleaning and removal of organic debris and dust, which if not removed may shield the virus from contact with the HP and hamper its efficacy. Application spaces generally must be completely sealed and dehumidified to a 10-70% relative humidity range; the time needed to dehumidify the space increases with the volume of the enclosure.[52] Ambient temperature also must be maintained at recommended levels throughout the fumigation process. If there are temperature gradients within the target area, micro-condensation may form earlier and in a greater quantity on cooler surfaces compared to warmer areas within the same room, leading to uneven vapor distribution throughout the target enclosure and potential reduced efficacy.[53] Ambient HP must be maintained at a set concentration over a minimum period of time to achieve the contact time to be effective. The HP concentration must be monitored with electrochemical sensors capable of measuring the ambient level of HP in the parts per billion and low parts per million levels to ensure an adequate concentration level is maintained throughout the entirety of the sterilization phase of the process. These HP chemical indicators must be placed throughout the enclosure being treated to verify adequate distribution of HP throughout the treatment process.

Foggers Not Recommended by EPA and the CDC for SARS-CoV-2

Likely for these reasons, historically, the CDC and EPA have discouraged the use of fogging/misting to disinfect buildings. In fact, both agencies have expressed concerns about the appropriateness of using fogging methods to disinfect hard impervious surfaces within buildings in the past.[54] Earlier this year, the EPA's Science Advisory Board concluded there is need for more research on whether "methods of application of List N products via fogging and/or electrostatic spraying provide the necessary contact time on surfaces to be efficacious against SARS-CoV-2."[55]

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[52] *See, e.g.*, TOMI™ Environmental Solutions, Inc., Environmental Binary Ionization Technology® (BIT") Solution is for use exclusively with the SteraMist™ Environment System.

[53] EPA, *Letter to Registrants of Antimicrobial Fogging/Misting Products* (April 1, 2013).

[54] *See* CDC, *Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings* (last updated February 15, 2017) ("[m]ore research is required to clarify the effectiveness and reliability of fogging, UV irradiation, and ozone mists to reduce norovirus environmental contamination. (No recommendation/unresolved issue)."); EPA, *Letter to Registrants of Antimicrobial Fogging/Misting Products* (April 1, 2013) ("Application by fogging/misting results in much smaller particle sizes, different surface coverage characteristics, and potentially reduced efficacy when compared to sanitization or disinfection product applications by spraying, sponging, wiping or mopping . . . The absence of pre-cleaning in the presence of soil contamination, potential reaction with or absorption of the active ingredient for different surfaces, and humidity/temperature fluctuations can also impact distribution and efficacy of the product . . . A surface treated by fogging/misting does not receive the same amount of active ingredient per unit area as the standard methods of application and, as a result, the level of efficacy actually achieved may not be the same level claimed on the label.").

[55] EPA, *Science Advisory Board Review: Identifying Research Needs to Address the Environmental and Human Health Impacts of COVID-19* (April 21, 2020).

The EPA continues to advise that "[u]nless the pesticide product label specifically includes disinfection directions for fogging, fumigation, wide-area or electrostatic spraying, or application via drones (i.e., unmanned aerial vehicles (UAV)), EPA does not recommend using these methods to apply disinfectants."[56] While EPA has implemented an expedited process for adding electrostatic sprayer use to List N, and has indicated it may consider UAV approval as "new data emerges," it has indicated no desire to expand the use of foggers or vaporizers for List N products. Given the current health crisis and the recognized data gap as to the efficacy of fogging/misting techniques, this silence is telling.

Conclusion

Commercial and institutional facility owners and operators should carefully select appropriate disinfectants and methods of application to ensure hard, impervious surfaces within interior spaces are safely and effectively disinfected. Only disinfectants on EPA's List N are authorized for use to treat building spaces for SARS-CoV-2. Important differences in the types of disinfectants and the methods of applying them and associated considerations of safety, efficacy, and practicality should be carefully weighed before choosing disinfectant means and methods. The use of conventional wipes for disinfection, consistent with product application label instructions, are proven, safe, and reliable. Fogging applications require careful analysis due to the complexity of use instructions and limitations on appropriate uses that must be strictly followed to ensure safety, efficacy, and compliance with FIFRA. The airborne nature of disinfectants applied by spraying and fogging and associated health risks pose special challenges that increase risks and costs and clearly are not a substitute for manual cleaning techniques.

[56] EPA, *Can I use fogging, fumigation, or electrostatic spraying or drones to help control COVID-19?, available at* https://www.epa.gov/coronavirus/can-i-use-fogging-fumigation-or-electrostatic-spraying-or-drones-help-control-covid-19#:~:text=Unless%20the%20pesticide%20product%20label,these%20methods%20to%20apply%20disinfectants.