Disinfectant Efficacy against the Wuhan Coronavirus

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Overview: The outbreak in Wuhan China of a newly identified coronavirus (colloquially the Wuhan Coronavirus) has raised questions about how various disinfectants will perform against this new virus when tested in standardized testing or when used in real-world applications. This document discusses our current understanding of these questions.

Disinfectant Testing: In the United States, disinfectants are tested for efficacy against pathogenic organisms using standardized methods approved by the United States Environmental Protection Agency (US-EPA). In Europe, EN standardized tests are used for the same purpose. These testing methods are developed to standardize evaluation of the performance of a chemical disinfectant against pathogenic microorganisms.

Lack of Sample Organism to Test: When new pathogenic microorganisms are identified, it is not always possible to run these standardized tests for a period of time as a 'standard' test organism or strain of organism must be decided, and then testing labs need to acquire samples of the organism. Even if testing were performed, the government registration process generally prevents a disinfectant manufacturer from promoting efficacy against an emerging pathogen until the government has reviewed and approved the claim. This is currently the case for the Wuhan Coronavirus. No commercial disinfectant on the market will have a claim for the Wuhan Coronavirus because it is currently not possible to test this virus and it is unlikely any disinfectant manufacturer will be able to promote such a claim for at least a year.

Hierarchy Approach:

Rutala and Weber (2014) proposed a hierarchy for anticipating disinfectant performance based on the general resistance to disinfection of the various classes of microorganisms. That table is shown below.

TABLE 5. Hierarchy of Microbial Resistance to Disinfectants and Sterilants

Microorganism	Examples
Prions	Creutzfeldt-Jakob disease agent, scrapie
Bacterial spores	*Bacillus, Geobacillus, Clostridium*
Protozoan oocytes[a]	*Cryptosporidium*
Helminth eggs[a]	*Ascaris, Enterobius*
Mycobacteria	*Mycobacterium tuberculosis, M. chelonae*
Small, nonenveloped viruses	Poliovirus, parvovirus, papilloma virus, norovirus
Protozoal cysts[a]	*Giardia, Acanthamoeba*
Fungal spores	*Aspergillus, Penicillium*
Gram-negative bacteria	*Pseudomonas, Escherichia*
Vegetative fungi and algae	*Aspergillus, Candida, Trichophyton*
Vegetative helminthes and protozoa[a]	*Ascaris, Giardia*
Large, nonenveloped viruses	Adenovirus, rotavirus
Gram-positive bacteria	*Staphylococcus, Enterococcus*
Enveloped viruses	Herpes, influenza, HIV, HBV

NOTE. Microorganisms are listed from the most resistant (prions) to the most susceptible (enveloped viruses) to disinfectants.[17] This hierarchical scale is only a guide to microbial susceptibility of pathogens to disinfectants, and it may vary depending on several factors (see text). Modified from McDonnell and Burke.[17] HBV, hepatitis B virus; HIV, human immunodeficiency virus.

[a] Many of the microbes listed are not causes of healthcare-associated infections.[17]

Diversey Inc, Suite 125
1300 Altura Road
Fort Mill, SC, 29708
www.diversey.com

The table lists enveloped viruses at the bottom as the easiest class of microorganism to kill and the Wuhan Coronavirus, as an enveloped virus, would be grouped with the other enveloped viruses. Consequently, we would expect any healthcare use disinfectant to be able to kill the Wuhan Coronavirus when used according to their label directions for concentration, contact time, and whether surfaces require precleaning, among other factors.

With the emergence of Ebola in 2014, the US-EPA developed a document called 'Draft Guidance to Registrants: Process for Making Claims against Emerging Viral pathogens not on EPA-Registered Disinfectant Labels, March 29, 2016'. This document also recognizes a hierarchy of kill and outlines the current kill claim on a disinfectant and how a disinfectant manufacturer may apply for a label exemption. The published criteria is:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, porous or non-porous surfaces.

2. The currently accepted product label (from an EPA registered product as described above in III.1) should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:

> a) A product should be approved by EPA to inactivate at least one large or one small non-enveloped virus **to be eligible for use against an enveloped emerging viral pathogen.**
>
> b) A product should be approved by EPA to inactivate at least one small, non-enveloped virus **to be eligible for use against a large, non-enveloped emerging viral pathogen.**
>
> c) A product should be approved by EPA to inactivate at least two small, non-enveloped viruses **to be eligible for use against a small, non-enveloped emerging viral pathogen**.

This guidance from US-EPA also demonstrates how a hierarchy approach is helpful in evaluating the potential efficacy of a chemical disinfectant on emerging pathogens.

Diversey sells disinfectants for healthcare use based on Accelerated Hydrogen Peroxide (AHP), sodium hypochlorite, quaternary ammonium chlorides, and peracetic acid. Any of these disinfectants would be expected to kill the Wuhan Coronavirus using standardized testing methods for enveloped viruses. Many of Diversey's healthcare use disinfectants carry claims against the human coronavirus, demonstrating specific efficacy against this family of viruses. Even without a coronavirus claim, Diversey's healthcare use disinfectants are expected to kill the Wuhan Coronavirus because of the low chemical resistance of coronaviruses. Also, many products have a claim for either large, non-enveloped viruses or small, non-enveloped viruses, which are tougher to kill than an enveloped virus. Until the laboratory testing can be run validating this thinking, we cannot make a specific label claim for this virus on any disinfectant.

Real World Use: There can be differences in performance for disinfectants between laboratory methods and the real world application. Often the presence of soil, inconsistent application, environmental conditions, and

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1300 Altura Road
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other factors reduce the effectiveness of disinfectants when used in the real world. The best way to minimize any differences in performance is to follow the label directions for the disinfectant.

Additionally, it is not clear what level of real-world performance is required to adequately protect people. Performance criteria built into the standardized testing methods in the US and Europe include a safety factor to allow for this difference in performance and a lack of clarify on the minimum efficacy required. Swabbing of surfaces can provide a validation of efficacy, but this is slow and expensive to perform.

Summary: In summary, any Diversey healthcare use disinfectant is expected to be able to kill the Wuhan Coronavirus. Until samples of the virus are available for testing, we cannot add a label claim to any of our products, but we explain through the hierarchy of resistance to disinfection discussed above how coronaviruses are quite easy to kill and that any healthcare use disinfectant sold by Diversey should be efficacious against this virus.

If there are any questions about this document, please contact Diversey Customer Service for further information.

References:

Rutala WA, Weber DJ. Selection of the ideal disinfectant. *Infect Control Hosp Epidemiol*. 2014; 35: 855-65

US-EPA. 'Draft Guidance to Registrants: Process for Making Claims against Emerging Viral pathogens not on EPA-Registered Disinfectant Labels, March 29, 2016". https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf

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