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The role of environmental disinfection in the healthcare setting is paramount in maintaining a low bioburden and helping prevent the role of fomites as a vector for disease transmission. Recent studies have shown that environmental contamination plays an important role in the transmission of Methicillin resistant *Staphylococcus aureus* (MRSA), Carbapenem Resistant Enterobacteriaceae (CRE), *Clostridium difficile* and Norovirus. For effective disinfection of the environmental surfaces in healthcare settings, users turn to Environmental Protection Agency (EPA) registered disinfectants.

# **Product Labels: A Source of Information and Cause for Confusion**

Product labels for EPA regulated disinfectants contain fundamental information for the user, such as key safety warnings and directions for use. The end user must refer to this information to select personal protective equipment, if necessary, first aid in the event of an accident, and surface disinfection contact times. While certain principle information is required, it can be difficult for the end-user to decipher the specific language used on one product versus another. Micro-organisms differ in their innate sensitivity to disinfectants, thus it is common to see varying contact times for different micro-organisms within the same use directions. Individual product labels are not all the same. Even products from the same manufacturer may carry different language and instructions for use. It should not be a surprise that these issues can lead to confusion and a lack of compliance.

Upon review of the commonly used disinfectant wipes currently available, we can see a number of different iterations of contact time directions for use:

- "Repeated use of the product may be required to ensure that the surface remains visibly wet."
- "Allow surface to remain wet for x minutes(s)."
- "Allow treated surface to remain wet for x minute(s)."
- "Allow surface to remain treated for the specific contact time."

### **Challenges and Flaws of Maintaining a Wet Surface**

Most manufacturers suggest that the end user maintain wetness for the duration of the contact time, even suggesting that additional wipes are to be used to maintain wetness. That appears to make sense, but there are

Users should wipe down the surface and allow the treated area to remain undisturbed for the given contact time.

flaws with this approach. First, there is the practicality of observing wetness, especially if the contact time is long (i.e. 10 minutes) – no healthcare worker has time to watch disinfected surfaces dry. Next, there is the subjectivity of wetness; is it thoroughly wet or partially wet? Wetness is truly subjective and therefore open to interpretation, which may impact how the product is used. Finally, consider the environmental conditions. Temperature, humidity and air flow all play a role in how long a disinfectant (or any liquid) will remain wet on a surface.

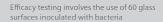
## **Surface Wetness and the EPA Testing Methodology**

For the truth, one needs to turn to the manner in which efficacy of disinfectants for hard non-porous surfaces are assessed by the EPA. In this example, we evaluate the method used for testing disinfectant wipes; the AOAC Germicidal Spray Test modified for towelettes<sup>1</sup>, although the same principal applies for ready to use spray formats. Succinctly, test micro-organisms are dried upon a glass surface prior to being treated by the disinfecting wipe in a standardized manner with environmental controls. Following the desired contact time, the glass surfaces are placed in growth medium to inactivate the active ingredient and determine if the test micro-organism(s) have been eradicated.

The contact time is determined based on testing by the manufacturer, but must be no more than ten minutes in accordance with the EPA regulations. During the contact time, the liquid delivered on the glass surface by the

# **EPA** Towelette Testing Methodology







Wipe glass surface • Allow treated surface to remain undisturbed for the given contact time • The surface is not assessed for wetness



After the contact time, transfer glass slide to neutralizing growth medium



Repeat for all 60 glass slides • Incubate and assess for the presence of the test organism

wipe is exposed to the air, simulating a typical healthcare environment. As such, the glass surfaces will exhibit varying levels of wetness according to the test conditions. Surfaces are not assessed for wetness and the EPA does not require test surfaces to remain wet during the test method.

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### **Making Sense of it All**

If the disinfectant time is not wet time, what is it? Users should wipe down the surface and allow the treated area to remain undisturbed for the given contact time. Regardless of whether the surface is wet, dry or somewhere in between, the efficacy is assured to be in line with the EPA registration.

**About the author:** James S. Clayton is a Research & Development (R&D) Director at <u>PDI</u>. He has 20 years of experience as a Microbiologist, specializing in surface disinfectants, and has supported over a dozen EPA disinfectant registrations throughout his career. James served on the European Committee for Standardization, as well as on ASTM technical advisory groups.

# **Exceptions: Additional Studies Required**

To assess efficacy versus *Clostridium difficile*<sup>2</sup> and *Candida auris*<sup>3</sup>, the EPA's interim guidance documents require disinfecting pre-saturated wipes (towelettes) to provide additional supporting evidence that the surface remains wet for the given contact time. The wetness determination study is in addition to the efficacy study and is detailed in footnote 3 under eligible product types.

#### PDI

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¹ Standard operating procedure for disinfectant test towelette testing: Testing of Staphylococcus aureus, Pseudomonas aeruginosa and Salmonella enterica. https://www.epa.gov/sites/production/files/2016-05/documents/mb-09-06.pdf

<sup>&</sup>lt;sup>2.</sup> C. difficile - Industry circulated document not in the public domain

<sup>3</sup> https://www.epa.gov/pesticide-registration/interim-guidance-efficacy-evaluation-products-claims-against-candida-auris-0