Technical Bulletin

ONE-STEP VS. TWO-STEP DISINFECTION

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Overview: In the US and Canada, manufacturers can select the test conditions used when testing their disinfectants for efficacy against certain pathogens. These test conditions are identified in the data submission to regulatory agencies, such as Health Canada or the United States Environmental Protection Agency (EPA), which review these submissions prior to registering these products for use.

One of the test conditions is whether to test in the presence of soil. Disinfectants can either be tested in the presence of 5% serum, which represents organic soil that may be present on surfaces when the disinfectant is used, or testing is performed without 5% serum which represents disinfecting on a pre-cleaned surface.

When disinfectants are tested in the presence of soil, they are referred to as single step (one-step) disinfectants, and are often called disinfectant cleaners. Those disinfectants that are not tested in the presence of soil are referred to as two-step disinfectants and are referred to as disinfectants but not disinfectant cleaners. This document discusses the major differences between the two.

Regulatory Framework: The manufacture and use of disinfectants is regulated by the Environmental Protection Agency (EPA) in the U.S. and Health Canada in Canada. Both regulatory agencies have similar disinfectant registration processes, offering manufacturers a range of testing options when submitting product efficacy data. The use solution (the ready-to-use product) of the disinfectant is tested according to a validated test method to determine whether the disinfectant is capable of killing a predetermined amount of the test pathogen under the test conditions. Passing the test allows the manufacturer to submit the data to the agency for the pathogen. Once reviewed and approved, it can be listed on the product label. Only microorganisms listed on the product label are allowed to be used in marketing the product.

As mentioned above, one of the options in selecting test conditions is whether or not to include 5% serum (organic soil) when testing the product. It is generally believed that passing the test is easier without soil (i.e. in “clean conditions”) than in the presence of soil (i.e. “dirty conditions”) as organic soil has been shown to interact with disinfectants and reduce the efficacy.

Facilities using the disinfectant will often require certain pathogens be listed on the product label before they will approve it for use in their facility. Thus there is an incentive for a registrant to pick testing conditions that favor passing the efficacy testing. It is important to understand the test conditions that were used during testing when selecting a disinfectant.

Clean Conditions: Disinfectants tested in clean conditions may not be as effective in the presence of soil. Depending on the disinfectant, the soil can protect the pathogen from biocidal activity of the active ingredient, the soil can inactivate the disinfectant, and the soil can slow the biocidal action of the active ingredient. As a result, if only clean conditions are selected (two

step disinfection), EPA and Health Canada both require that the disinfectant be labeled to include a step to clean surfaces before disinfecting and a second step to disinfect. The facility may use any cleaner for the cleaning step or may use the disinfectant, but the key point is that these disinfectants always require two steps to disinfect surfaces.

Dirty Conditions: If the disinfectant is tested in the presence of 5 % serum (representing soil), the testing result has demonstrated that the disinfectant is effective even if soil is present, and low levels of soil do not significantly affect the efficacy of the disinfectant. Since pathogens and soil are often invisible to the eye, having a product that can work in the presence of incidental soil can be a significant benefit. For one-step disinfectants, a separate cleaning step is not required.

Thus the test conditions used during registration should be taken into account when determining what disinfectant to use as this affects the cleaning and disinfection process. The process takes significantly longer when using a two-step process versus a single step process. Using products that can clean and disinfect in one step can significantly speed the process vs. those requiring two steps.

Label Directions: For both one-step and two-step disinfectants, the product label will often include instructions regarding the removal of heavy (gross) soils. When excessive soil is present (i.e. a blood or body fluid spill), it may limit the effectiveness of disinfectants. Thus the manufacturer will frequently advise the user to pre-clean the surface to remove the heavy soil. The pre-cleaning step is not required for small amounts (i.e. incidental amounts) of soil when using a one-step disinfectant cleaner, so a certain amount of judgment may need to be exercised by the user in determining whether to pre-clean when using a one-step disinfectant cleaner. After pre-cleaning any heavy soils:

A. For one-step disinfectants, the worker can clean and disinfect with a single application.
B. For two-step disinfectants, the worker must first clean the surface and then apply the disinfectant as a second step.

To illustrate how this might appear on a product label, below are two excerpts from disinfectant wipes labels:

> Product A: “Use a wipe to remove heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for one full minute.”

Product A was tested in the presence of soil, so it advises the user to first remove heavy soil and then to clean and disinfect in a single step. If there is no heavy soil, the user can clean and disinfect in a single step with no pre-cleaning.

> Product B: “Cleaning Instructions: Use one towelette to completely pre-clean surface of all gross debris. For use as a disinfectant: Use a second towelette to thoroughly wet the surface.”

Product B explicitly calls out the need to clean surfaces before disinfecting. However, they do not also advise the user to first pre-clean gross soils. Thus the user can easily confuse the steps

and think that the cleaning step is optional when there is no heavy soil, when in fact it is always required with a two-step disinfectant irrespective of soil load. In the presence of heavy soil, a standard cleaning step should still follow gross soil removal before disinfecting the surface.

Diversey uses the following language on its Oxivir Tb Wipes.

A. For use as a one-step cleaner disinfectant
    a. Pre-clean heavily soiled areas.
    b. Pull towelette from canister and wipe hard non-porous environmental surfaces.
    c. All surfaces must remain visibly wet for 1 minute. (…)
    d. Allow to air dry or rinse with potable water if necessary.

In this example, the manufacturer's instructions explicitly advise the user to remove any heavy soils and then clean and disinfect in a single step.

Summary: It is important to review the testing methods used by manufacturers to determine the efficacy of their products. As shown, there is a significant advantage to using a one-step disinfectant to improve the simplicity and productivity of the disinfection process by ensuring that a disinfectant can work in the presence of soil. If there are any questions about this assessment or any Diversey products, please contact Diversey Customer Technical Support at 1-800-558-2332, option 5.