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INFORMATION SHEET

EN 16615 - New efficacy test for surface disinfectants reflecting practical application of chemical disinfectants employing wipes

Type of Study: Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)

Author/Publisher: Based on EN 16615:2015

INTRODUCTION

The European Standard EN 14885, which defines the tests to be performed, test conditions and application areas (e.g. surface disinfection in healthcare), represents the basis for determining the test methods relevant to the application area.

The EN 14885 requires all available efficacy testing of disinfectants in a tiered approach, proving efficacy first in a suspension test under conditions of practice (contact time, organic soil, temperature) and second using test organisms attached to a representative surface simulating the true application of the product (EN phase 2 step 1 and step 2). A European phase 2 step 2 test for surface disinfectants applied by wiping has not been available until recently. This is why Ecolab surface disinfectants were tested according to the German DGHM guideline 2001. Now this gap has been closed by implementation of EN 16615: 2015. Also the new German VAH guideline (replacing DGHM 2001) has harmonized this test.

METHODS

This is the first European test truly simulating disinfecting surfaces by wiping. On a defined PVC surface an area is marked, contaminated with the test organism and dried. Three more areas are marked and kept sterile. This is why the test is also called a "4-field-test". After drying the whole area is wiped across the four marked test fields, starting in front of field 1, turning immediately after test field 4 and wiped back to the starting point with the disinfectant. This can either be done with a standard wipe wetted with a standardized amount of disinfectant or for products supplied as ready-to-use wipes using these directly. At the end of the contact times all four marked areas are assessed for microbial contamination. For the first (primarily contaminated) area the microbial reduction is calculated as log R. For the other (primarily sterile) surfaces the spread of test organisms from the first field is evaluated. Hence, both targets of surface disinfection are assessed at the same time: killing of microbes in contaminated places and avoiding spread of microbes by wiping.

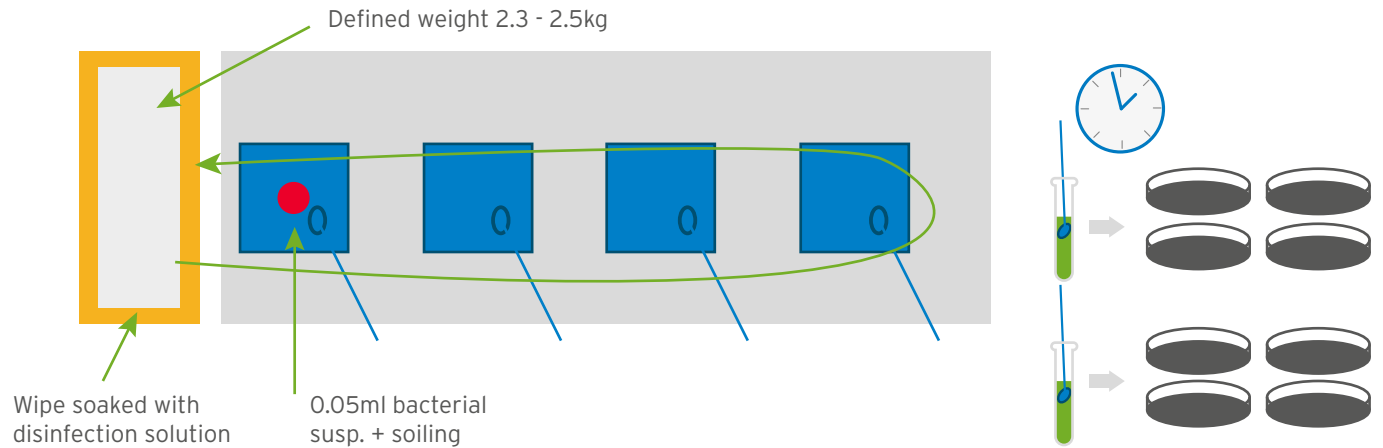
PASS CRITERIA / RESULTS

For the reduction of test organisms in the primarily contaminated area, 5 log R (bacteria) and 4 log R (yeasts) are defined as pass criteria. Only a defined minor spread of test organisms to primarily sterile surfaces is accepted (field number 2 to 4). EN 16615 so far supports bactericidal and yeasticidal efficacy claims only. For other efficacy spectra such a test is formally not available yet. The standard wipe material used for products not supplied as ready-to-use wipes is regarded representative of all commonly used cleaning textiles. Therefore the result is valid, whatever cleaning textile will be used in practice. An exception to this rule are pre-soak systems such as Ecolab's Incidin wipes, where wipes and disinfectant use solution are stored together for a prolonged time. In this case, the specific wipe should be tested with the specific disinfectant after the defined storage time of the combination.

WHAT DOES THAT MEAN FOR OUR PRODUCTS?

Products tested according to EN 16615 represent the latest state of the art in surface disinfection. Ecolab uses the same methodology also to support wider efficacy spectra, like fungicidal, tuberculocidal, mycobactericidal and even sporicidal effects. The method represents real practice conditions: The surface is wiped once only and then left to dry. The frequently asked question, whether a surface must be kept wet for the entire contact time, hence, is obsolete. For a product tested according to this standard it is obvious that the product will work to achieve the desired effect during the contact time after wiping the surface once and then leaving it to dry.

TEST DESIGN ACC. EN 16615



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