

Rationale for the use dilution shelf life of Sekusept® aktiv

1. Introduction

Sekusept® aktiv is a disinfectant powder for medical devices. The components of this formulation release the active ingredient of the product – peroxyacetic acid (POAA) – upon dissolution in water. After dissolution it takes 15 min to reach a POAA concentration desirable for disinfection. The concentration then reaches a characteristic maximum after approximately 1 hour. After this the concentration slowly decreases again and reaches an ineffective range after a longer time.

2. Determination for lower POAA concentration limit for efficacy

Tests were run with an aged 2% solution of Sekusept® aktiv. POAA was determined with a standard titration method after different time points. The two most difficult to inactivate test organisms, namely Poliovirus and bacterial spores were chosen for these experiments, to make sure, worst case conditions were represented.

For virucidal efficacy, the most resistant non-enveloped test virus, the Poliovirus was chosen. Tests were run as suspension tests according to EN 14476. Even under organic load the virus was completely inactivated at a concentration of 1000 ppm (mg/l) POAA as determined by a standard titration technique within 10 min¹⁾.

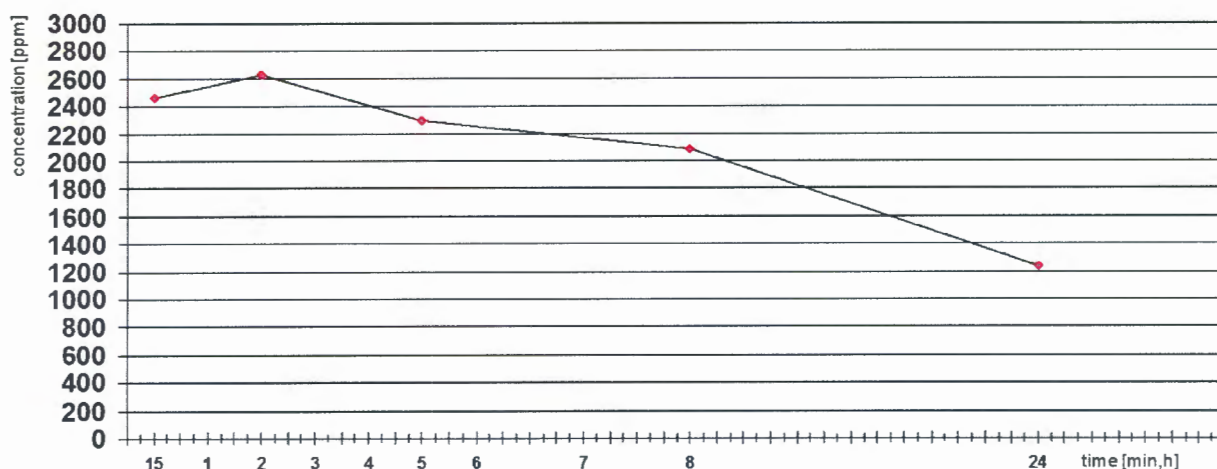
Bacillus subtilis was chosen to test the most resistant bacterial forms, spores in a suspension test according to EN 13704. Tests were performed at 1000 ppm POAA (as determined by a standard titration technique). A complete kill of the test organism was achieved under clean conditions after 15 min²⁾.

1) test report Henkel Microbiological Services 08.00771

2) test report Henkel Microbiological Services 08.00772

3. Development of POAA in a Sekusept® aktiv use dilution

The development of POAA in a 2% Sekusept® aktiv use dilution in tap water is shown in the following diagram as determined by a standard titration technique:



The data indicates that after 15 min of dissolution time POAA concentration is well above 1000 ppm. After 24 h the use dilution has still a POAA concentration above 1000 ppm.

4. Conclusion

The efficacy tests indicate that a concentration of 1000 ppm POAA in a use solution is high enough to fulfill all efficacy claims of this product (bactericidal, yeasticidal, sporicidal, and virucidal) within a contact time of 15 min. Even if tests according to other guidelines may recommend longer contact times, to fulfill certain efficacy claims, these data indicate that this concentration is sufficient at the corresponding contact time.

The POAA concentration in a 2% use dilution of Sekusept® aktiv reaches more than 1000 ppm after 15 min and remains >1000 ppm for 24 hours in unsoiled tap water. This indicates a use dilution shelf life of 24 h under unsoiled conditions.

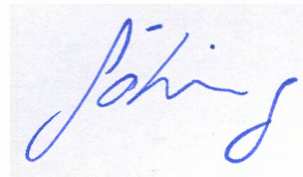
Since not all local conditions (water quality, soiling under specific use conditions) can be tested in the laboratory, it is recommended to verify the use dilution shelf life under local conditions using dedicated test strips, which indicate POAA concentration of Sekusept® aktiv solutions.

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