Is polyhexamethylene-guanidine hydrochloride (PHMGH) sporidical? A critical review

The antimicrobial active agent or biocidal substance polyhexamethylene-guanidine hydrochloride (PHMGH) belongs to the chemical group of guanidines. This chemical group is broadly used in skin and wound antiseptics, wound dressings and surface disinfectants. It is also represented by the well-known active agents chlorhexidine digluconate (CHG) and polyhexamethylene biguanide (PHMB). It has been proposed that the active agents of this group are bactericidal and active in killing yeasts (yeasticidal), but not active against bacterial spores or moulds (Kaehn, 2010; Hübner et Kramer, 2010). Based on this general assumption, the results of Oulé et al. (2012) were surprising. At first sight, this paper suggests that a sporidical efficacy of PHMGH against Bacillus subtilis spores was shown. In addition, the same group has published data on the fungicidal efficacy of PHMGH (Koffi-Nevry et al., 2011). Especially as the concentrations used were low and the exposure times for the respective efficacies were very short for both references studies, these would be ground-breaking results for this active agent and the whole chemical group of guanidines.

Therefore, our group reviewed the methodology used for the efficacy testing to check whether the efficacy of the PHMGH was overestimated by Oulé et al. (2012) and Koffi-Nevry et al. (2011).

As we were not able to purchase the active agent PHMGH or the mentioned disinfectant, we were not able to perform efficacy testing under controlled conditions in our laboratory. Therefore, we reviewed the studies published by Oulé et al. (2012) and Koffi-Nevry et al. (2011) to compare the methodology used with current standard practice, e.g. that published by ASTM (2005) and CEN (2001, 2002), to show the efficacy of PHMGH against bacterial spores of B. subtilis, and fungal spores, e.g. of Aspergillus spp., Mucor spp. and Penicillium spp. We found significant differences in the methodology. In both articles, the publication by Oulé et al. (2008) is referenced for a description of the method. Therefore, this paper was also taken into consideration.

The review of the studies published by Oulé et al. (2008, 2012) and Koffi-Nevry et al. (2011) showed that none of the published state of the art methods was used to determine the sporidical and fungicidal efficacies of PHMGH. For fungicidal efficacy testing, for example, the method described by CEN (2001) would be appropriate. For sporidical efficacy testing, the method detailed by ASTM (2005) or CEN (2002) would be appropriate.

The neutralization method has not been described in detail in the papers by Oulé et al. (2008, 2012) and Koffi-Nevry et al. (2011). The neutralizing method was invalid according to the most widely accepted published methods which are, for example, described by ASTM (2013) and CEN (2001, 2002).

For generating new scientific data, appropriate and widely accepted methods have to be used. In the studies published by Oulé et al. (2008, 2012) and Koffi-Nevry et al. (2011), this general scientific criterion has not been followed. Therefore, in our opinion the validity of the presented data is questionable.

All guanidines and biguanides, including PHMGH as well as PHMB and CHG, are difficult to neutralize because of their surface-active character. However, the inactivation step is essential to be able to differentiate between sporistatic (growth inhibition of bacterial spores) and sporidical (killing of bacterial spores) efficacy. Only certain specific methods are therefore sufficient to inactivate these agents after the contact time. If the neutralization step is insufficient, the active agent remains partially active during the determination of the residual microbial count and the efficacy is overestimated (Kampf et al., 2005). Bacteria and fungal spores are sensitive to such agents and do not germinate in the presence of low doses of antimicrobials. As the inactivation procedure (washing with distilled water) that was used to generate the efficacy data for PHMGH in the publications by Oulé et al. (2008, 2012) and Koffi-Nevry et al. (2011) was in our experience insufficient, a solely sporistatic effect was measured. The positively charged, surface active agent PHMGH will cover the surface of the bacterial and fungal spores and inhibit the germination of the respective spores. The spores will only germinate under optimal conditions, which are not present with PHMGH outside the cell. A sufficient neutralizer for PHMGH might, in our experience, consist of substances such as polysorbate 80, asolectin and SDS. As such a neutralizer was not employed, we consider that the data do not show the sporidical or fungicidal efficacy of PHMGH.

We recommend retesting the efficacy of the mentioned disinfectant and/or the active agent to present valid data on the specific efficacy of PHMGH. This may either confirm or not confirm the data presented by Oulé et al. (2008, 2012) and Koffi-Nevry et al. (2011), but in any case would support the credibility of the important and clinically interesting active agent PHMGH.

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CEN (2001). Chemical Disinfectants and Antiseptics – Quantitative Non-Porous Surface Test for the Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants used in Food, Industrial, Domestic and Institutional Areas – Test Method and Requirements Without Mechanical Action (Phase 2/Step 2); EN 13697. European Committee for Standardization (CEN), Brussels, Belgium.

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