



LONZA Paper

A Comparison Study of Disinfectant Cleaners based on Hydrogen Peroxide or

Abstract

In an industry that relies on valid information flow in terms of accuracy and integrity, Virox maintains high standards. As a company that publishes fact based, peer reviewed data; we respect and welcome the opinion of impartial industry experts. The LONZA document is an **internally generated** report that contains a multitude of misleading statements and unrealistic comparisons in their favour. The reader must take into consideration the motive the architect of such a document might have.

Background

In February 2002, LONZA Group conducted an internal study comparing one of Virox's Accelerated Hydrogen Peroxide-based formulations sold under the name Virox 5 and one of Virox's Stabilized Hydrogen Peroxide-based formulations sold under the name Hydrox Disinfectant Cleaner. The formulations tested in 2002 were DIN registered products available only to the Canadian market. While Virox has brought several AHP-based products to market in the USA, the formulations tested by LONZA are not available as EPA registered disinfectants.

The approach proposed by Virox for environmental surface sanitation in the healthcare market is based on the widely accepted Infection Control Guidelines published by Health Canada and the CDC, wherein general housekeeping (i.e. floors, walls, etc) is performed with a good detergent, and high touch environmental surfaces and non-critical patient care items are treated with a registered disinfectant. With this concept in mind, Hydrox Disinfectant Cleaner, a 3% Stabilized Hydrogen Peroxide formulation, was developed for use at a 1:64 dilution and 1:256 as a good detergent for general housekeeping. At full strength, Hydrox carries a 10-minute Hospital Grade Disinfection claim for use in such situations as cleaning of large blood and body fluid spills. Virox 5 was designed to provide rapid broad-spectrum kill for non-critical surfaces in general; that is, surfaces likely to be contaminated with not only vegetative bacteria, but with enveloped and non-enveloped viruses as well. In concentrate Virox 5 is a 7% Accelerated Hydrogen Peroxide formulation. At the use dilution of 1:16, which corresponds to an active level of hydrogen peroxide of approximately 0.437%, Virox 5 not only destroys bacterial species (as measure by both the AOAC methods 991.48 and 991.49 and by the more stringent Quantitative Carrier Test of Sattar et al (ASTM, 2001)), but also inactivates the more resistant hydrophilic (non-enveloped) viruses. Additionally at both a 1:64 and 1:128 dilutions, Virox 5 does indeed destroy vegetative bacteria by greater than 100,000-fold

(99.999%) in suspension testing under the presence of a 5% soil challenge in 30 seconds, hence the label claim Broad-Spectrum Sanitizer.

Technical Review of the Lonza Group Document:

The Microbial Efficacy and Time Kill sections of this document compares the bactericidal activity of Lonza Formulation S-21 to both Accelerated Hydrogen Peroxide (Virox 5) and Stabilized Hydrogen Peroxide (Hydrox) and highlights the first of many unrealistic comparisons.

First, in accordance to the product label, Hydrox is registered as a disinfectant when used at full strength. The Lonza document has disregarded the products label instructions and has tested Hydrox at both a 1:32 and 1:64 dilutions. While not a registered disinfectant at either of these dilutions and therefore, not expected to pass disinfection tests, the results as shown in Table 1 indicate that while Hydrox has limited activity against *Staphylococcus aureus*, it is quite efficacious against *Pseudomonas aeruginosa*. As expected at the dilutions listed on the label for disinfection, both Virox 5 and the Lonza formulation passed. With respect to the Time Kill assay again the Lonza document strives to lead the reader astray. Virox 5 as noted on the label carries a sanitizing claim at the 1:64 and 1:128 dilution and would not be expected to achieve disinfection. More importantly, is the misrepresentation of the efficacy of the Lonza S-21 formulation. The EPA approved label is registered using a 10-minute contact time. One should question, why a company would choose to register a product using a contact time of 10-minutes when the testing they are reporting in this comparison document uses a contact time of 5-minutes. This puts into question the validity of these test results and whether the experiments were performed under biased conditions to improve the efficacy of the Lonza S-21 formulation as compared to AHP.

Secondly, what the Lonza document fails to investigate is a comparison of each of the individual product's virucidal activity. As mentioned above, Virox 5 at the 1:16 dilution is effective against both enveloped (easy to kill) and non-enveloped viruses at a contact time of 5-minutes. By contrast, it is well known that quaternary ammonium compounds are largely ineffective against non-enveloped viruses (Block, 2001). For example, formulation S-21 (as referenced in the Lonza document) is effective against easy to kill enveloped viruses at a 1:64 dilution but, requires a 1:16 dilution to be effective against the relatively susceptible Adenovirus type 5 (a semi-enveloped virus), and

PTSHH0133.0(06/2015)



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at a contact time of 10-minutes (Lonza, 1007). The net result is a surface which may potentially still pose a serious risk for viral infection transmission, even after being treated at longer contact times.

The Cleaning Performance section does not refer to a specific, industry accepted test method. The assessment of cleaning performance should also be performed by standardized techniques and test soils in order to be valid. Test soils can be designed and manipulated to favour cleaning by certain types of formulations, and to show impaired cleaning by others. In Canada, the standard for measuring cleaning of liquid solutions is CAN/CGSB-2.11-94, Method 20.3. Two additional well accepted methods are that of the American Society for Testing and Materials (ASTM Method 4488 and ASTM Method 5343). Both Virox 5 and Hydrox have been tested by an accredited third party laboratory using the CAN/CGSB-2.11-94 method with a % soil reduction of 86.5% and 75% respectively. The Virox 5 formulation as been further tested using both ASTM Method 4488 and 5343 with results of 68.7% and 83.9%. In general, data not generated by methodology sanctioned by well-known professional associations such as the Canadian General Standards Boards, or the American Society for Testing and Materials should be viewed with caution.

Similar to the measurement of cleaning efficiencies, the quantification of materials compatibility should also always be performed according to standardized methodology. One such method is the National Association of Corrosion Engineers standard method TM-01-69, which involves the calculation of corrosion rates to metals under conditions of continuous immersion. Results obtained with protocols other than those recognized by national or international standards should always be handled with care. Nonetheless, it is certainly expected that an oxidizing solution will have certain effect on unprotected carbon steels such as cold-rolled AISI 1010. However, since carbon steels are more suited for use in the erection of the hospital building infrastructure rather than for hygienic surfaces and items destined for health care, one has to ponder on their relevance in evaluation of disinfectant compatibility. On the other hand, the in-use dilution of AHP has been formally tested by internationally recognized methodology, and by an accredited independent private laboratory, finding it to be non-corrosive to skin and eyes. These results render the composition of no corrosive at its in-use dilution.

Conclusion

The selection of a chemical disinfectant for a particular application can be a non-trivial endeavour, generally requiring the consideration of several factors such as germicidal efficacy and spectrum of action, cleaning performance, potential for occupational and environmental hazards, compatibility to materials and surfaces, cost of use, and organoleptic characteristics (i.e. odour). Different individuals will place more or less importance on one of more of these performance characteristics. In most cases, however, the main selection criteria for infection control practitioners are a broad spectrum of activity, and the ability to perform rapidly, even under the presence of soil. AHP meets these requirements, as it is proven to possess wide germicidal action (bacteria and enveloped and non-enveloped viruses), rapid speed of kill (5-minutes), and benign occupational, environmental and organoleptic profiles.

PTSHH0133.0(06/2015)